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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION**

FULFILLIUM, INC.,

Plaintiff,

vs.

RESHAPE MEDICAL LLC, SV
HEALTH INVESTORS, LLC,
INTERSECT PARTNERS, LLC AND
RESHAPE LIFESCIENCES, INC.

Defendants.

Case No. 8:18-cv-01265-RGK-PLA

**FIRST AMENDED COMPLAINT
FOR TRADE SECRET
MISAPPROPRIATION AND
PATENT INFRINGEMENT**

DEMAND FOR JURY TRIAL

1 Plaintiff Fulfillium, Inc. (“Fulfillium” or “Plaintiff”), for its
2 Complaint against ReShape Medical LLC (“ReShape Medical LLC”), SV
3 Health Investors, LLC (“SV Health”), Intersect Partners, LLC (“Intersect
4 Partners”), and ReShape Lifesciences Inc. (“ReShape
5 Lifesciences”)(collectively “Defendants”) alleges the following:

6 **NATURE OF THE ACTION**

7 1. This is an action for trade secret misappropriation and patent
8 infringement arising under the Uniform Trade Secrets Act, CA. Civ. Code §3426
9 *et seq.* and/or Mass. Gen. Laws ch. 93, § 42-42A and the Patent Laws of the
10 United States, 35 U.S.C. § 1 *et seq.*

11 **THE PARTIES**

12 2. Fulfillium is a corporation organized and existing under the laws of
13 the State of Delaware, with an address at 1136 Orchard Avenue, Napa, California
14 94558.

15 3. On information and belief, ReShape Medical LLC is a limited
16 liability company organized and existing under the laws of the State of Delaware
17 with its principal place of business at 100 Calle Iglesia, San Clemente, California
18 92672. ReShape Medical LLC can be served via its registered agent The
19 Corporation Trust Company, Corporation Trust Center, 1209 Orange Street,
20 Wilmington, Delaware, 19801. ReShape Medical LLC is a wholly owned
21 subsidiary of ReShape Lifesciences and the surviving entity of the merger of a
22 subsidiary of ReShape Lifesciences and ReShape Medical, Inc.

23 4. On information and belief, SV Health is a limited liability company
24 organized and existing under the laws of the State of Delaware with its principal
25 place of business at One Boston Place, 201 Washington Street, Suite 3900,
26 Boston, Massachusetts 02108. SV Health Investors can be served via its registered
27 agent The Corporation Trust Company, Corporation Trust Center, 1209 Orange
28

1 Street, Wilmington, Delaware, 19801. SV Health maintains a business in the
2 State of California at 1700 Owens Street, Suite 585, San Francisco, CA 94158.

3 5. On information and belief, ReShape Lifesciences is a corporation
4 organized and existing under the laws of the State of Delaware with its principal
5 place of business at 1001 Calle Amanecer, San Clemente, California 92673.
6 ReShape Lifesciences can be served via its registered agent The Corporation Trust
7 Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.
8 ReShape Lifesciences is the corporate parent of ReShape Medical LLC and
9 ultimate bearer of certain liabilities of the now merged and extinguished entity,
10 ReShape Medical, Inc.

11 6. On information and belief, Intersect Partners is a limited liability
12 company organized and existing under the laws of the State of Nevada with places
13 of business in Nevada and Minnesota. Intersect Partners can be served via its
14 registered agent Sierra Corporate Services – Reno, 100 West Liberty Street 10th
15 Floor, Reno, NV 89501.

16 7. On information and belief, ReShape Medical LLC's predecessors,
17 ReShape Medical, Inc. and Abdominis, Inc. ("Abdominis") were founded, funded,
18 owned and controlled in relevant respect through a joint venture between by SV
19 Life Sciences, LLC, which has reorganized as SV Health Investors, LLC and
20 Intersect Partners.

21 8. The website of SV Health Investors states that "SV Health Investors,
22 formerly SV Life Sciences, is a leading healthcare and life sciences venture
23 capital and growth equity firm." SV Health Investors and its predecessor SV Life
24 Sciences have at all relevant times held one or more seats on ReShape Medical,
25 Inc.'s Board of Directors.

26 9. The first heading of the About Us page of SV Health Investors'
27 website is "Hands-on business partners." Exhibit 5. The page explains that SV
28 Health Investors "work hands-on with our portfolio companies as trusted advisers

1 and partners from formation to exit. We help them develop business strategy,
 2 make connections within our networks, and guide them through both smooth and
 3 turbulent times toward a successful exit.” *Id.* According to the website, “[t]he SV
 4 team has more than 400 aggregate years of healthcare operating experience –
 5 which means we can work as true partners with our entrepreneurs, and develop
 6 strong relationships with them through the full life cycle of their ventures.” *Id.*

7 10. On information and belief, SV Health and its predecessor SV Life
 8 Sciences along with Intersect Partners have directed, controlled, actively induced
 9 and/or conspired with ReShape Medical, Inc., and subsequently ReShape Medical
 10 LLC, to take the actions that form the basis for this Second Amended Complaint.

11 11. Upon information and belief, Intersect Partners and SV Health have
 12 jointly managed ReShape Medical since its inception.

13 12. On October 2, 2017, EnteroMedics, Inc. acquired ReShape Medical,
 14 Inc. for cash and securities in the value of approximately \$38 million. This
 15 acquisition and merger was announced on October 3, 2017.
 16 <http://ir.enteromedics.com/releasedetail.cfm?ReleaseID=1042545>. ReShape
 17 Medical LLC is an additional entity that resulted from this merger. On October
 18 23, 2017, EnteroMedics, Inc. announced its name change to ReShape Lifesciences
 19 Inc. <http://ir.enteromedics.com/releasedetail.cfm?ReleaseID=1044913>.

20 **JURISDICTION AND VENUE**

21 13. Upon information and belief, each of ReShape Medical LLC and
 22 ReShape Lifesciences sells and offers to sell products and services throughout the
 23 United States, including in this judicial district, and introduces products and
 24 services into the stream of commerce that incorporate infringing technology
 25 knowing that they would be sold in this judicial district and elsewhere in the
 26 United States.

27 14. This is an action for trade secret misappropriation and patent
 28 infringement arising under the Uniform Trade Secrets Act, CA. Civ. Code §3426

1 *et seq.* and/or Mass. Gen. Laws ch. 93, § 42-42A, and the Patent Laws of the
2 United States, Title 35 of the United States Code, respectively.

3 15. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331
4 and 1338(a).

5 16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b),
6 (c), and (d). On information and belief, each Defendant conducts business in this
7 district, the claims alleged in this Complaint arise in this District, and acts of trade
8 secret misappropriation and infringement have taken place and are continuing to
9 take place in this District.

10 17. Venue is proper in this judicial district under 28 U.S.C. § 1400(b).
11 On information and belief, ReShape Medical LLC and ReShape Lifesciences have
12 committed acts of infringement in this District and have a regular and established
13 place of business within this District.

14 18. On information and belief, each Defendant is subject to this Court's
15 general and specific personal jurisdiction because each Defendant has sufficient
16 minimum contacts within the State of California and this District, pursuant to due
17 process and/or the California Long Arm Statute, because each Defendant
18 purposefully availed itself of the privileges of conducting business in the State of
19 California and in this District, because each Defendant regularly conducts and
20 solicits business within the State of California and within this District, and
21 because Fulfillium's causes of action arise directly from each Defendant's
22 business contacts and other activities in the State of California and this District.

23 **GENERAL ALLEGATIONS**

24 19. Dr. Richard D. Y. Chen was born in Taiwan in 1958 and emigrated to
25 the United States in 1972. Dr. Chen obtained an undergraduate degree in
26 biochemistry and molecular biology from Harvard University in 1979. Dr. Chen
27 next attended medical school at Northwestern University and obtained an M.D. in
28

1 1983. Dr. Chen performed his internship in general surgery and continued in his
2 residency in neurosurgery at the Johns Hopkins Hospital in the 1980's.

3 20. Dr. Chen obtained a Master's Degree in Business Administration
4 from Stanford University in 1990. Following matriculation, Dr. Chen began
5 working in the investment banking department at Morgan Stanley & Company.
6 Thereafter, Dr. Chen continued working in financial services making investments
7 in and assisting start-up companies primarily in the technology sector.

8 21. In 1999, Dr. Chen started conceiving innovative ideas of his own by
9 combining his experiences at the crossroads of medicine and technology. After
10 the tragic events of September 11, 2001, prospects in the technology investment
11 markets began to slow. Dr. Chen decided to focus on developing and
12 commercializing these ideas into entrepreneurial ventures.

13 22. Dr. Chen conceived of a bariatric medical device and procedure
14 whereby a novel balloon device is delivered endoscopically to reduce the interior
15 volume of the stomach and impede the flow of ingested food and thereby
16 effectively reduce the calories consumed. To mitigate potentially fatal
17 consequences of premature rupture and migration, which were significant
18 deficiencies in earlier devices within this class, safety was provided by two or
19 more chambers filled with fluids.

20 23. Because obesity is a complex, multifactorial disease, Dr. Chen
21 invested at least two years' time i) analyzing critically over a thousand scientific
22 papers relating from the genetic basis of obesity to interventions in clinical
23 therapy to the psychosocial impact of the disease, and ii) attending scientific
24 research conferences on the basic underpinnings of the field and major medical
25 conferences in the United States and overseas to learn about the state of the art in
26 therapy and how the various medical specialties played their role in its treatment.
27 Gaining insight from these activities, Dr. Chen further refined key elements of his
28 idea and its implementation into everyday medical practice.

1 24. Dr. Chen then presented his idea, on a confidential basis, to leading
2 researchers and clinicians in the field, including the former presidents of the
3 American Gastroenterology Association, the American Society of Bariatric
4 Surgeons and its overseas counterpart, the International Federation for the Surgery
5 of Obesity. Practically everyone he contacted responded favorably with the
6 willingness to commit to participate further in developing the medical device and
7 procedure. Each of these disclosures was subject to a mutual understanding and
8 obligation of confidentiality. Only individuals who were under written
9 obligations of confidentiality were provided information regarding Fulfillium's
10 trade secrets.

11 25. Dr. Chen contributed funds and his intellectual property to form
12 Fulfillium, Inc. in 2004 and filed his first provisional patent application on May 3,
13 2004. Dr. Chen raised seed capital from friends and family to take the idea to the
14 next stage of development. Dr. Chen attended trade shows in medical device
15 manufacture. Dr. Chen engaged consultants including engineers to help develop
16 the device and former regulators to explore the pathway for FDA approval.
17 Prototypes were constructed and animal lab facilities were evaluated.

18 26. Dr. Chen next embarked on raising venture capital to prove the
19 concept. Given his past experience in the venture business, Dr. Chen adopted a
20 set of practices for disclosure to protect the intellectual properties he developed.
21 Under this set of practices, Dr. Chen did not disclose any trade secret information
22 to anyone unless he had confirmed an agreement that it would be kept
23 confidential. On January 25, 2005, Dr. Chen spoke with Dr. Samuel Wu, M.D. of
24 SV Life Sciences (predecessor of SV Health) to discuss Fulfillium's technology
25 on a confidential basis. All parties confirmed that the conversations regarding Dr.
26 Chen's ideas were subject to an oral agreement of confidentiality. On February
27 10, 2005, Dr. Chen attended a meeting including the SV Life Sciences team in
28 Boston led by partner David Milne via a videoconference call hosted at the SV

1 Life Sciences offices at 950 Tower Lane, Ste. 1535, Foster City, California. Dr.
2 Chen understood the meeting to be confidential and, consistent with that, Dr.
3 Chen's presentation slides were all marked "STRICTLY CONFIDENTIAL." All
4 parties confirmed that the conversations surrounding this meeting were subject to
5 an oral agreement of confidentiality.

6 27. In addition, SV Life Sciences representatives had due diligence calls
7 with various Fulfillium scientific advisors. These due diligence phone calls were
8 for expert validation of Fulfillium's therapeutic concept and did not include
9 presentations of Fulfillium's product development plans or trade secrets.

10 28. Dr. Wu informed Dr. Chen that the due diligence was "looking good"
11 and that SV Life Sciences was contemplating a term sheet. Dr. Wu noted that
12 although he, in California, had taken a point person role in the development of the
13 deal, SV Life Sciences' medical device group was headquartered in Boston and he
14 was not part of the group. Thus, going forward SV Life Sciences would prefer to
15 partner with a venture capital firm in California who could more effectively
16 monitor Fulfillium's activities.

17 29. Among other venture capital firms, Dr. Chen separately gave a
18 confidential presentation to Sprout Partners. Dr. Chen delivered the presentation
19 to Sprout partners Jeani Delagardelle at Sprout's Menlo Park office and Andrew
20 Firlik, M.D. via conference call on March 4, 2005. Sprout and Fulfillium
21 understood that the conversations surrounding this presentation were confidential
22 because the parties previously signed and executed a written non-disclosure
23 agreement. Ms. Delagardelle later invited Dr. Chen to attend as Sprout's guest at
24 the annual American Heart Association luncheon, a key event in the industry. Ms.
25 Delagardelle took on a lead role by referring another venture capital firm as a
26 potential co-investor. Dr. Chen eventually made an introduction between SV Life
27 Sciences and Sprout.

1 30. During the foregoing meetings and communications with SV Life
2 Sciences and Sprout, Dr. Chen provided confidential and detailed disclosures of
3 Fulfillium's preferred clinical trial design and regulatory approval strategy. All of
4 the relevant parties to the foregoing meetings and communications understood the
5 conversations that occurred were subject to either oral or written agreements of
6 confidentiality.

7 31. On information and belief, neither SV Life Sciences nor Sprout had
8 any substantial previous knowledge or experience with balloon treatments for
9 obesity.

10 32. On information and belief, all of SV Life Sciences' and Sprout's
11 knowledge concerning Dr. Chen's novel balloon designs for obesity as of the
12 Spring of 2005 was supplied by Dr. Chen.

13 33. In the Spring of 2005, Ms. Delagardelle indicated that the due
14 diligence process would be delayed somewhat due to the fact that the healthcare
15 group principals of Sprout were forming a new firm, New Leaf Venture Partners.
16 Ms. Delagardelle asked Dr. Chen if this would pose a problem. Dr. Chen
17 responded that time was of the essence but a short delay under the circumstances
18 would be manageable.

19 34. Meanwhile, Dr. Chen continued to interface with SV Life Sciences.
20 SV Life Sciences arranged for Dr. Chen to meet George Wallace (venture partner
21 for SV Life Sciences) on May 16, 2005 at a restaurant in Chicago. During the
22 meeting Mr. Wallace proposed terms and conditions under which he would work
23 with Fulfillium. In addition to other compensation, Mr. Wallace demanded
24 greater than 25% stake in Fulfillium after the first round of financing by venture
25 capital firms. Given the ownership dilution that typically occurs during the first
26 round of financing, Mr. Wallace was effectively demanding majority ownership of
27 Fulfillium. Dr. Chen noted that Mr. Wallace's requested equity share was more
28 than two to four times greater than that typically allotted to a CEO brought in to

1 run a company at Fulfillium's stage of development. Mr. Wallace offered no
2 justification other than to say that he needed to compensate his business partner, a
3 practicing radiologist in Minnesota, and would not proceed without including his
4 business partner. Dr. Chen never disclosed the trade secrets to Mr. Wallace.

5 35. Thereafter, no further discussion took place between Mr. Wallace and
6 Dr. Chen. Instead, unbeknownst to Dr. Chen, decision makers in SV Life
7 Sciences sought to launch a new company with Mr. Wallace as the CEO based on
8 Fulfillium's technology and trade secrets, which were misappropriated despite the
9 repeated oral agreements of confidentiality with SV Life Sciences. In the early
10 summer of 2005, Ms. Delagardelle of New Leaf sent a brief email to Dr. Chen
11 advising that New Leaf was considering a deal that SV Life Sciences was
12 proposing. Dr. Chen presumed that SV Life Sciences was proposing bringing to
13 market an alternative solution that would be different from the technology
14 developed and confidentially disclosed by Dr. Chen. Dr. Chen would later
15 discover that SV Life Sciences' venture headed by Mr. Wallace was premised not
16 on some alternative solution but rather Fulfillium's technology and trade secrets.

17 36. On information and belief, Mr. Wallace's new company, called
18 Abdominis, Inc., was formed during the summer of 2005 and was funded by New
19 Leaf, Intersect Partners, and SV Life Sciences. Upon information and belief, each
20 of SV Life Sciences, Intersect Partners, and New Leaf not only provided capital,
21 but acted in concert to provide direct guidance in the company's development and
22 controlled the operations of the company through their board membership.

23 37. Abdominis was subsequently renamed ReShape Medical, Inc.
24 Hereafter, "Reshape Medical, Inc." will refer to Abdominis, Inc. and its successor-
25 in-interest Reshape Medical, Inc.

26 38. As is typical for a medical start-up company, ReShape Medical, Inc.
27 operated in "stealth mode" during development. ReShape Medical, Inc. started
28 pivotal clinical trials in 2012 and applied for FDA approval in 2014. The FDA

1 granted Pre-Marketing Approval to the ReShape Duo™ device and treatment
2 method on July 28, 2015.

3 39. When ReShape Medical, Inc. emerged from stealth mode and began
4 commercial operations, Dr. Chen learned that ReShape Medical, Inc. had copied
5 his trade secrets, including his entire clinical trial “playbook.” ReShape Medical,
6 Inc. copied, among other things, Dr. Chen’s clinical trial design and his selection
7 of the principal investigator.

8 40. On information and belief, the board of directors and officers of
9 ReShape Medical, Inc. knew or had reason to know of the foregoing facts and
10 events at the time ReShape Medical, Inc. first submitted the ReShape Duo™
11 product for FDA approval in 2012.

12 41. On October 2, 2017, EnteroMedics, Inc. acquired ReShape Medical,
13 Inc. for cash and securities in the value of approximately \$38 million. This
14 acquisition and merger was announced on October 3, 2017.
15 <http://ir.enteromedics.com/releasedetail.cfm?ReleaseID=1042545>. ReShape
16 Medical LLC is an additional entity that resulted from this merger. On October
17 23, 2017, EnteroMedics, Inc. announced its name change to ReShape Lifesciences
18 Inc. <http://ir.enteromedics.com/releasedetail.cfm?ReleaseID=1044913>.

19 42. Upon information and belief, as a result of the aforementioned
20 merger, ReShape Medical LLC and ReShape Lifesciences Inc. are the entities that
21 now hold the liabilities of ReShape Medical, Inc. Fulfillium reserves the right to
22 include additional entities if it later discovers that ReShape Medical, Inc.’s
23 liabilities have been transferred elsewhere as a result of the aforementioned
24 merger.

COUNT I – TRADE SECRET MISAPPROPRIATION

43. Fulfillium repeats the allegations of paragraphs 1-42 above as though fully set forth herein.

44. This claim is asserted against ReShape Medical LLC, Intersect Partners, and SV Health for misappropriation of Fulfillium's trade secrets and for conspiring to misappropriate such trade secrets.

45. The specific trade secrets that ReShape Medical, Inc., Intersect Partners, SV Health, and/or their agents misappropriated, despite the repeated oral and/or written agreements of confidentiality, include at least three aspects of Dr. Chen's clinical trial "playbook." Three key protocols in the playbook optimized the experimental rigor of the trial, especially in combination, in contrast to the typical product development approach to optimize the conditions for favorable outcomes. The first is the counterintuitive control arm that "stacked the deck" against the experimental arm. To tease out efficacy due to the device alone, the device therapy had to show statistically better results over the most efficacious non-interventional therapy available, namely diet and exercise counseling. The second is the trial primary and secondary endpoints that set high bars for not just efficacy but clinical efficacy. To gain acceptance in the bariatric scientific community, not only the results have to be statistically significant, but the difference between the two arms had to be wide enough to warrant an interventional device therapy. The third is the counterintuitive and gastric device-focused principal investigator selection premise. To provide even further confidence in the results to overcome the stigma of gastric balloons, the trial was to be conducted under the watchful eyes of investigators of consummate skill and reputation. All of the above were developed after Dr. Chen's extensive study of the shortcomings of previous gastric devices.

46. Upon information and belief, based on EnteroMedics's acquisition of ReShape Medical, Inc. and the publically available regulatory documents relating

1 to said merger, ReShape Medical LLC assumed all, or at least a portion of, the
2 liabilities of ReShape Medical, Inc., including the present trade secret
3 misappropriation claims. To the extent that ReShape Medical LLC has taken on
4 the liability of ReShape Medical, Inc., it is liable for ReShape Medical, Inc.'s
5 misappropriation; and/or to the extent ReShape Medical LLC continues to rely on
6 and/or profit from ReShape Medical, Inc.'s misappropriation, it is liable for that
7 continuing activity. Fulfillium reserves the right to assert this count against
8 additional entities if it later discovers that ReShape Medical, Inc.'s liabilities have
9 been transferred elsewhere as a result of the aforementioned merger.

10 47. The disclosures of each of these three trade secrets were made
11 pursuant to the aforementioned written and/or oral agreements of confidentiality
12 to SV Life Sciences, Intersect Partners and New Leaf. On information and belief,
13 these trade secrets were conveyed to Mr. Wallace, Intersect Partners, ReShape
14 Medical LLC and SV Health who each used them for their own benefit.

15 48. A significant portion of the information used by ReShape Medical,
16 Inc. to design its device and obtain FDA approval constitute Fulfillium trade
17 secrets in that they: (a) constitute information that derives independent economic
18 value from not being generally known to the public or to other persons who can
19 obtain economic value from its disclosure or use; and (b) have been the subject of
20 reasonable efforts to maintain their secrecy.

21 49. Through SV Life Sciences (SV Health) and Intersect Partners (and
22 their misappropriation of Dr. Chen's trade secrets, which were protected via
23 repeated confidentiality agreements), Mr. Wallace, and Sprout, ReShape Medical
24 LLC, Intersect Partners, and SV Health acquired confidential, expert validated,
25 trade secret information about all aspects of Fulfillium's business, including
26 clinical trial design and regulatory strategy. Specifically, ReShape Medical LLC,
27 Intersect Partners, and SV Health misappropriated at least the three
28 aforementioned aspects of Dr. Chen and Fulfillium's clinical trial playbook.

1 50. Upon information and belief, ReShape Medical LLC, Intersect
2 Partners, and SV Health have relied upon and used that trade secret information in
3 some or all aspects of its business, including commitment to launch, raising
4 capital, product design, procedure design, and FDA clinical trial design.

5 51. The actions alleged above constitute a wrongful misappropriation of
6 Fulfillium's trade secrets. They also constitute a wrongful conspiracy among the
7 board directors and officers of and investors in ReShape Medical LLC, Intersect
8 Partners, and SV Health to misappropriate Fulfillium's trade secrets.

9 52. As a direct and proximate result of the actions alleged above,
10 Fulfillium has been shut out of the market. By misappropriating Fulfillium's
11 technology and launching a competing company, ReShape Medical LLC, Intersect
12 Partners, and SV Health prevented Fulfillium from raising the funds required to
13 bring its product to market.

14 53. As a direct and proximate result of the actions alleged above,
15 ReShape Medical LLC, Intersect Partners, and SV Health have been unjustly
16 enriched in an amount no less than the business opportunity deprived from
17 Fulfillium.

18 54. In doing the acts hereinabove alleged, each of ReShape Medical
19 LLC, Intersect Partners, and SV Health and its investors have engaged in willful
20 and malicious misappropriation by reason thereof, and Fulfillium is entitled, as
21 against each of them, to twice the amount of its actual damages and/or the
22 amounts by which ReShape Medical LLC, Intersect Partners, and SV Health have
23 been unjustly enriched as exemplary damages pursuant to Civil Code § 3426.3(c)
24 and/or Mass. Gen. Laws ch. 93, § 42-42A.

25 55. By the aforesaid acts, ReShape Medical LLC, Intersect Partners, and
26 SV Health have irreparably injured Fulfillium and such injury will continue unless
27 enjoined by this Court.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 9,456,915

56. Fulfillium repeats the allegations of paragraphs 1-55 above as though fully set forth herein.

57. On October 4, 2016, U.S. Patent No. 9,456,915 (“the ‘915 patent”), entitled “Methods, Devices, and Systems for Obesity Treatment,” was duly and legally issued by the United States Patent and Trademark Office. A true and correct copy of the ‘915 patent is attached as Exhibit 1.

58. Fulfillium is the assignee and owner of the right, title and interest in and to the ‘915 patent, including the right to assert all causes of action arising under said patents and the right to any remedies for infringement of them by at least an assignment dated July 16, 2018. (Ex. A.)

59. On information and belief, ReShape Medical LLC and ReShape Lifesciences are engaged in the business of making, using, selling, offering to sell, and/or importing medical devices. A description of ReShape Medical LLC and ReShape Lifesciences’ business is available on its business website, which is located at <http://pro.reshapeready.com>; <https://reshapeready.com/>. A screenshot of the homepage of ReShape Medical LLC’s business website is attached as Exhibit 3.

60. As part of its business, each of ReShape Medical LLC and ReShape Lifesciences makes, uses, offers to sell, sells, and/or imports a dual intragastric balloon for weight loss, including ReShape’s “Duo Balloon” device, which is placed inside the patient’s stomach for weight loss. ReShape Medical LLC and ReShape Lifesciences have purposefully sold and offered for sale such Duo Balloon devices throughout the United States.

61. Upon information and belief, each of ReShape Medical LLC and ReShape Lifesciences has and continues to directly infringe at least claims 1-2 and 4-27 of the ‘915 patent by making, using, selling, importing and/or providing and causing to be used medical devices for weight loss, including but not limited to,

1 those sold under the name ReShape Duo Balloon (the “Infringing
2 Instrumentalities” or “ReShape Balloon”). For clarity the terms “Infringing
3 Instrumentalities” and “ReShape Balloon” are understood to include the balloon
4 device intended for delivery into the gastric cavity, as well as any delivery system
5 for that balloon device.

6 62. Representative claim 1 of the ‘915 patent recites a “gastric balloon
7 structure for deploying in a gastric cavity of a patient, comprising: at least two
8 isolated non-concentric inflatable chambers, wherein each chamber of the at least
9 two isolated non-concentric inflatable chambers has a respective inflated state
10 volume such that deflation of any single chamber of the at least two isolated non-
11 concentric inflatable chambers leaves the inflated state volume of the remaining
12 chambers of the at least two isolated non-concentric inflatable chambers
13 unaffected.” The Infringing Instrumentalities infringe claim 1 of the ‘915 patent.
14 The ReShape Dual Balloon “is a temporary implant designed to facilitate weight
15 loss by occupying space in the stomach.” ReShape™ Integrated Dual Balloon
16 System Instructions for Use, PN 03-0300 Rev. D, p. 1,
17 [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
18 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below,
19 taken from ReShape’s instruction manual, shows the dual balloon in a patient’s
20 stomach. The ReShape website states that “[i]n the unlikely event of individual
21 gastric balloon leakage or deflation, the independently sealed *ReShape* weight loss
22 balloons are designed to minimize risk of migration or obstruction.”
23 <http://pro.reshapeready.com/about-reshape/#theadvantages>. In other words, each
24 balloon inflates and deflates independently. *See also*
25 <https://www.youtube.com/watch?v=U91FsjtMf3o>.

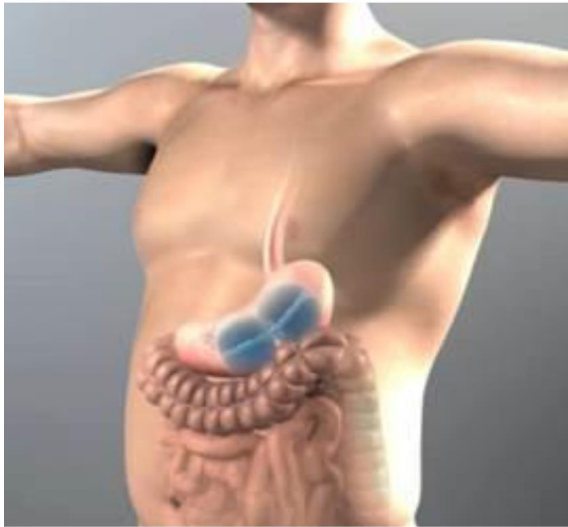


Figure 1. *ReShape* Dual Balloon in the Stomach

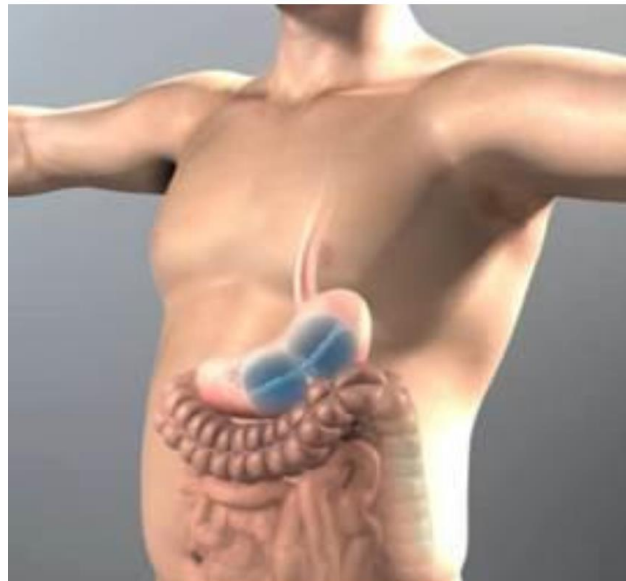
63. Claim 1 further recites “a valve system for introducing a fluid into the at least two isolated non-concentric inflatable chambers and for retaining, upon inflation, the fluid in the at least two isolated non-concentric inflatable chambers.” The chambers of the *ReShape* balloons are filled after they are positioned in the patient’s stomach. *ReShape™ Integrated Dual Balloon System Instructions for Use*, PN 03-0300 Rev. D, pp. 16-17, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. “The *ReShape™* Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; U.S. Pat. No. 8,142,469 at Fig. 1, 3-5.

64. Claim 1 further recites “a flexible central spine spanning a gap between and fixedly attached to both a first chamber of the at least two isolated non-concentric inflatable chambers and a second chamber of the at least two isolated non-concentric inflatable chambers; wherein the gastric balloon structure, in its inflated state, assumes a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity, such that the flexible central spine flexibly conforms, upon at least partially filling the at least two isolated non-

1 concentric inflatable chambers, the gastric balloon structure to the natural three-
2 dimensional kidney shape of the gastric cavity.” The flexible central spine
3 element is illustrated in the video provided on ReShape’s website, a frame from
4 which is reproduced below. *See* <https://reshapeready.com/reshape-cc/>; *see also*
5 <https://www.youtube.com/watch?v=U91FsjtMf3o>.



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12 The conformance of the dual balloon to the stomach of the patient is shown in the
13 image above and is also illustrated in Figure 1 of ReShape’s instructions for use,
14 reproduced below.



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25 **Figure 1. ReShape Dual Balloon in the Stomach**

26 65. The final recitation in claim 1 is that “a respective fluid volume for
27 filling each chamber of the at least two isolated non-concentric inflatable
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1 chambers is selected based upon dimensions of the gastric cavity of the patient.”

2 ReShape’s instructions for use state as follows:

3 2.4. Determine the desired inflation volume for each balloon. A fill volume of
4 375 cc is recommended for patients < 64.5” in stature and 450 cc for patients ≥
5 64.5” in stature.

6 See <https://reshapeready.com/wp->

7 content/uploads/2015/07/ReShape_Instructions_For_Use.pdf at 16. ReShape
8 instructs the user to determine the size of the patient and to select a corresponding
9 fill volume for the balloon structure.

10 66. Claim 2 generally recites the gastric balloon structure of claim 1,
11 wherein the gastric balloon structure is designed to provide for modulated passage
12 of food through the gastric cavity upon inflation.

13 67. The Infringing Instrumentalities infringe claim 2 of the ‘915 patent.
14 The ReShape Dual Balloon “is a temporary implant designed to facilitate weight
15 loss by occupying space in the stomach.” ReShape™ Integrated Dual Balloon
16 System Instructions for Use, PN 03-0300 Rev. D, p. 1,
17 <https://reshapeready.com/wp->
18 content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. The figure below,
19 taken from ReShape’s instruction manual, shows the dual balloon in a patient’s
20 stomach providing modulated passage of food through the gastric cavity upon
21 inflation.
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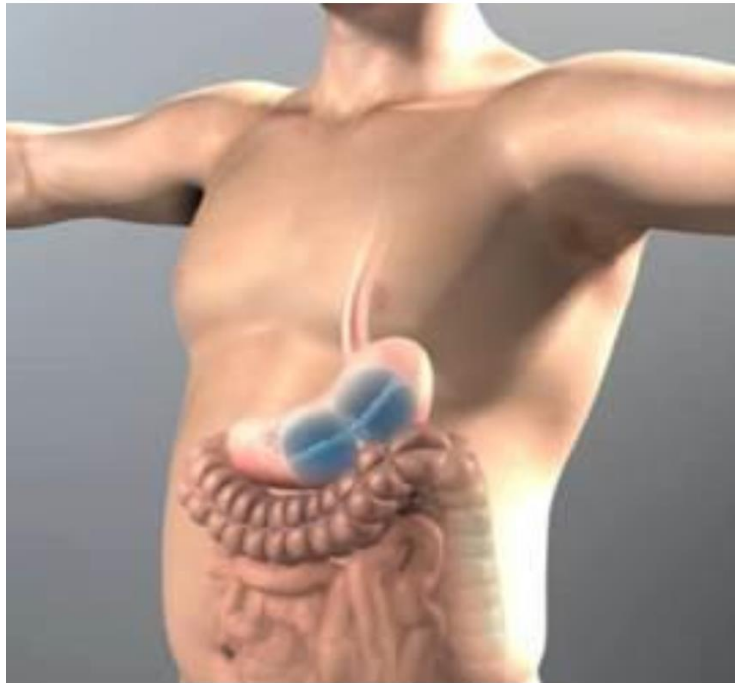


Figure 1. ReShape Dual Balloon in the Stomach

68. Claim 4 generally recites the gastric balloon structure of claim 1, wherein, upon inflation, the gastric balloon structure is configured to rest within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

69. The Infringing Instrumentalities infringe claim 4 of the ‘915 patent. The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>. Accordingly, on information and belief, it is configured to rest within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

70. Claim 5 generally recites the gastric balloon structure of claim 4, wherein an outer surface of each of the isolated non-concentric inflatable chambers is configured to align against greater and lesser curvatures of the gastric cavity.

71. The Infringing Instrumentalities infringe claim 5 of the '915 patent. The ReShape Dual Balloon mimics "the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient's anatomy and enhance tolerability." See <http://pro.reshapeready.com/about-reshape/#theadvantages>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape's instructions for use, reproduced below.

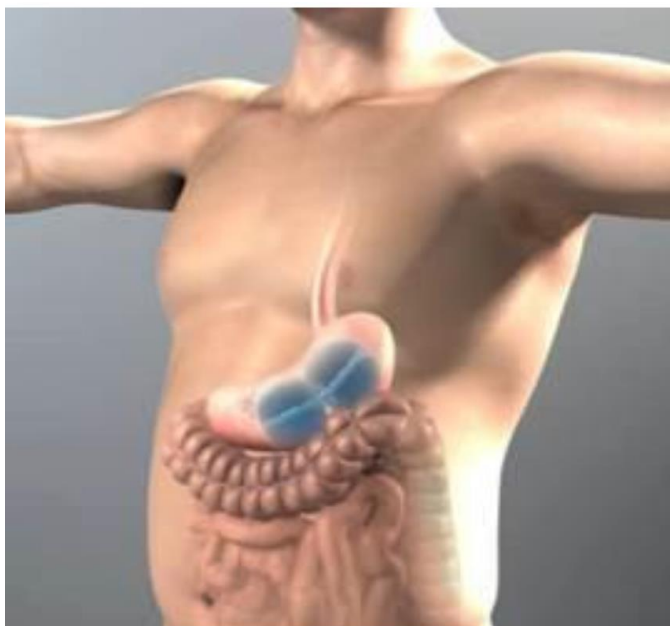
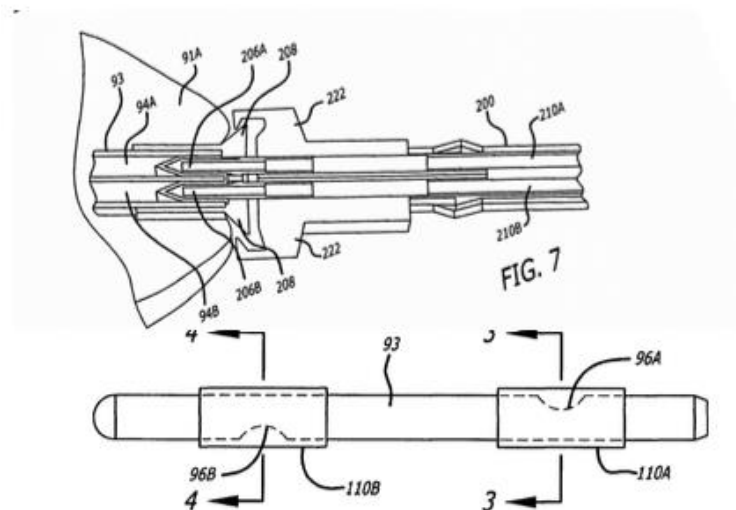


Figure 1. *ReShape* Dual Balloon in the Stomach

1 Accordingly, on information and belief, an outer surface of each of the isolated
2 non-concentric inflatable chambers is configured to align against greater and
3 lesser curvatures of the gastric cavity.

4 72. Claim 6 generally recites the gastric balloon structure of claim 1,
5 wherein the valve system comprises a respective valve structure for introducing
6 fluid into each chamber of the at least two isolated non-concentric inflatable
7 chambers, wherein each respective valve structure includes at least two valves in
8 series.

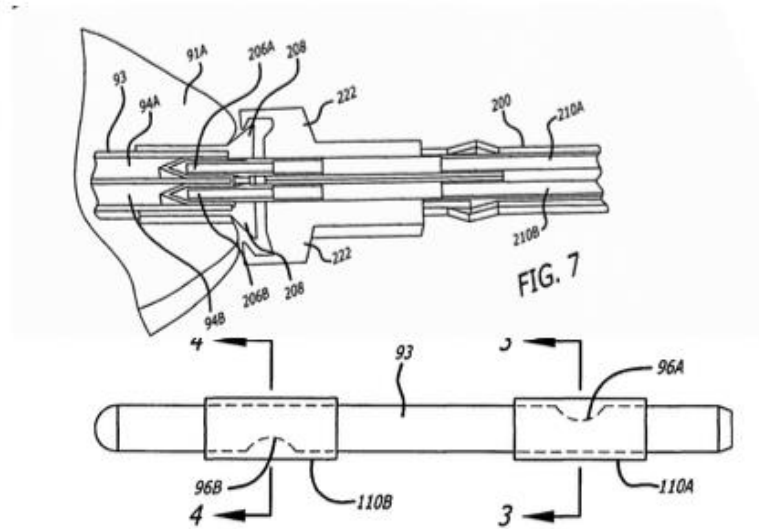
9 73. Upon information and belief, the Infringing Instrumentalities infringe
10 claim 6 of the '915 patent. The chambers of the ReShape balloons are filled after
11 they are positioned in the patient's stomach. ReShape™ Integrated Dual Balloon
12 System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17,
13 [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
14 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). "The ReShape™
15 Valve Sealant is necessary to seal the device valves and prevent balloon leakage."
16 *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; Further,
17 ReShape's patent, U.S. 8,142,469, shows two valves in series as shown below at
18 206A and 96A:



1 Accordingly, on information and belief, the ReShape Balloon valve system
2 comprises a respective valve structure for introducing fluid into each chamber of
3 the two isolated non-concentric inflatable chambers, wherein each respective
4 valve structure includes at least two valves in series.

5 74. Claim 7 generally recites the gastric balloon structure of claim 6,
6 wherein a first valve structure of a first chamber of the at least two isolated non-
7 concentric inflatable chambers includes a one-way valve in series with an
8 additional one-way valve.

9 75. Upon information and belief, the Infringing Instrumentalities infringe
10 claim 7 of the '915 patent. The chambers of the ReShape balloons are filled after
11 they are positioned in the patient's stomach. ReShape™ Integrated Dual Balloon
12 System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17,
13 [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
14 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). "The ReShape™
15 Valve Sealant is necessary to seal the device valves and prevent balloon leakage."
16 *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; Further,
17 ReShape's patent, U.S. 8,142,469, shows two one-way valves in series as shown
18 below at 206A and 96A:



Accordingly, on information and belief, the ReShape Balloon valve structure includes a one-way valve in series with an additional one-way valve.

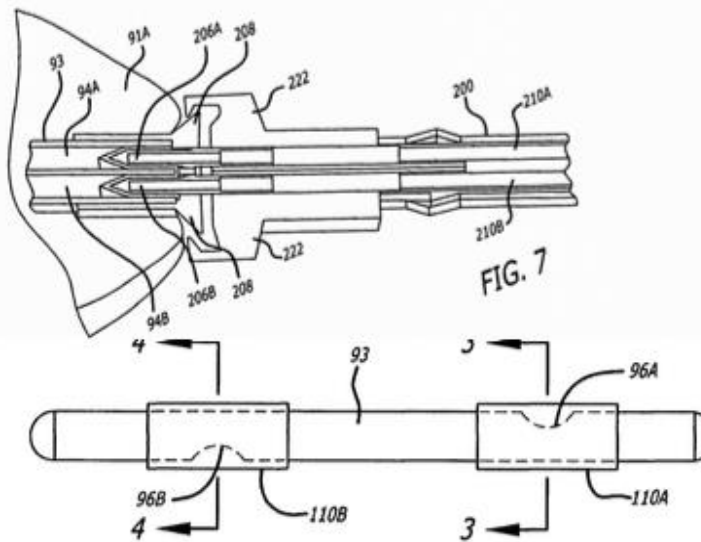
76. Claim 8 generally recites the gastric balloon structure of claim 1, wherein the flexible central spine is in fluid communication with the valve system.

77. Upon information and belief, the Infringing Instrumentalities infringe claim 8 of the '915 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below.

See <https://reshapeready.com/reshape-cc/>; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>.



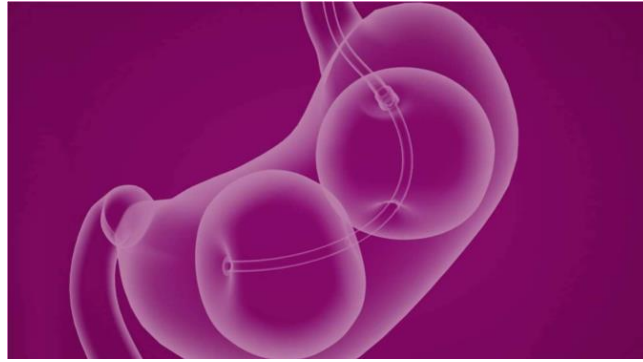
Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



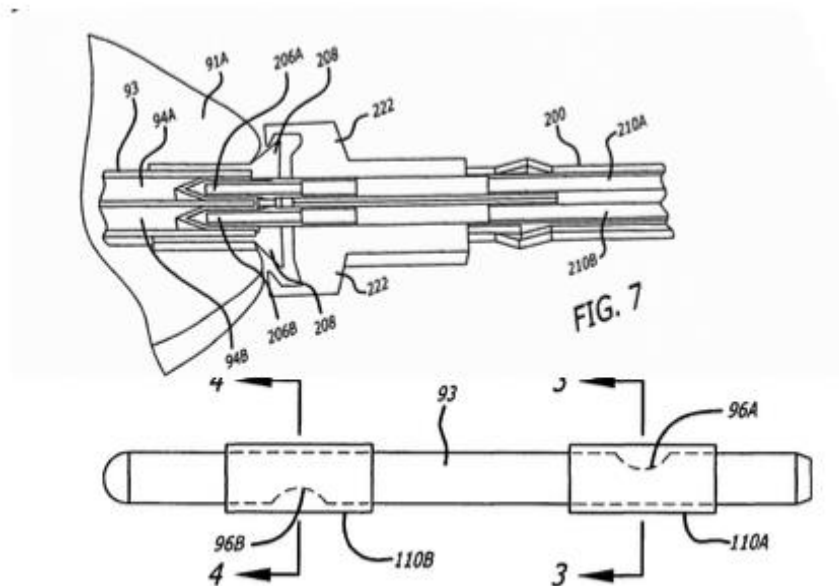
Accordingly, on information and belief, the ReShape Balloon's flexible central spine is in fluid communication with the valve system.

78. Claim 9 generally recites the gastric balloon structure of claim 8, wherein the flexible central spine encloses an inflation lumen for introducing the fluid into the at least two isolated non-concentric inflatable chambers.

79. Upon information and belief, the Infringing Instrumentalities infringe claim 9 of the '915 patent. The chambers of the ReShape balloons are filled after they are positioned in the patient's stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. "The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage." *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See* <https://reshapeready.com/reshape-cc/>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



Accordingly, on information and belief, the ReShape Balloon's flexible central spine encloses an inflation lumen for introducing the fluid into the at least two isolated non-concentric inflatable chambers.

80. Claim 10 generally recites the gastric balloon structure of claim 1, wherein the gastric balloon structure is designed to maintain the introduced volume of fluid while deployed in the gastric cavity of the patient without controlled adjustment.

1 81. The Infringing Instrumentalities infringe claim 10 of the ‘915 patent.
2 The ReShape dual balloons are both filled with saline and remain at a generally
3 fixed volume until they are removed. *See*
4 <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
5 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p.
6 15-16, [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
7 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf).

8 82. Claim 11 generally recites the gastric balloon structure of claim 1,
9 wherein each chamber of the at least two isolated non-concentric inflatable
10 chambers is filled with a same fluid.

11 83. The Infringing Instrumentalities infringe claim 11 of the ‘915 patent.
12 The ReShape dual balloons are both filled with saline and remain at a fixed
13 volume until they are removed. *See*
14 <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
15 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p.
16 15-16.

17 84. Claim 12 recites “a method for treating obesity in a patient,
18 comprising: measuring one or more dimensions of a gastric cavity of the patient in
19 a feeding state” The ReShape Dual Balloon “is a temporary implant
20 designed to facilitate weight loss by occupying space in the stomach.” ReShape™
21 Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1.
22 ReShape’s instructions for use state as follows:

23 2.4. Determine the desired inflation volume for each balloon. A fill volume of
24 375 cc is recommended for patients < 64.5” in stature and 450 cc for patients ≥
25 64.5” in stature.

26 *See* [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
27 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf) at 16. ReShape
28

1 instructs the user to determine the size of the patient and to select a corresponding
2 fill volume for the balloon structure.

3 85. Claim 12 further recites “determining, based on the one or more
4 dimensions of the gastric cavity, a respective fill volume for each chamber of a
5 plurality of inflatable-space filling chambers of an obesity treatment device”
6 ReShape’s instructions for use state as follows:

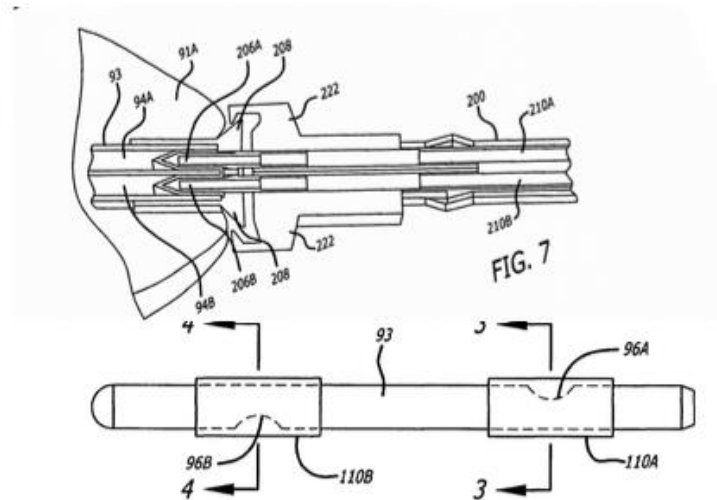
7 2.4. Determine the desired inflation volume for each balloon. A fill volume of
8 375 cc is recommended for patients < 64.5” in stature and 450 cc for patients ≥
64.5” in stature.

9 See [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
10 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf) at 16. ReShape
11 instructs the user to determine the size of the patient and to select a corresponding
12 fill volume for the balloon structure.

13 86. Claim 12 further recites “positioning the obesity treatment device in
14 the gastric cavity in a deflated state” The chambers of the ReShape balloons
15 are filled after they are positioned in the patient’s stomach. ReShape™ Integrated
16 Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17,
17 [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
18 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The ReShape™
19 Valve Sealant is necessary to seal the device valves and prevent balloon leakage.”
20 *Id.*

21 87. Claim 12 further recites “after positioning, at least partially filling
22 each chamber of a plurality of inflatable space-filling chambers of the obesity
23 treatment device with the respective volume of a same type of fluid via a valve
24 system, wherein the respective volumes of fluid remain unadjusted during
25 treatment[.]” The chambers of the ReShape balloons are filled after they are
26 positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System
27 Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, <https://reshapeready.com/wp->
28

content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. The ReShape dual balloons are both filled with saline and remain at a fixed volume until they are removed. *See* <https://www.youtube.com/watch?v=U91FsjtMf3o>; https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf, Sec. 2.1 – 2.7 at p. 15-16. “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; Further, ReShape’s patent, U.S. 8,142,469, shows two valves in series as shown below at 206A and 96A:



88. Claim 12 further recites “wherein the obesity treatment device assumes a natural three-dimensional kidney shape of the gastric cavity such that, upon at least partially filling the chambers, an outer surface of the obesity treatment device aligns against greater and lesser curvatures of the gastric cavity” The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape’s instructions for use, reproduced below.

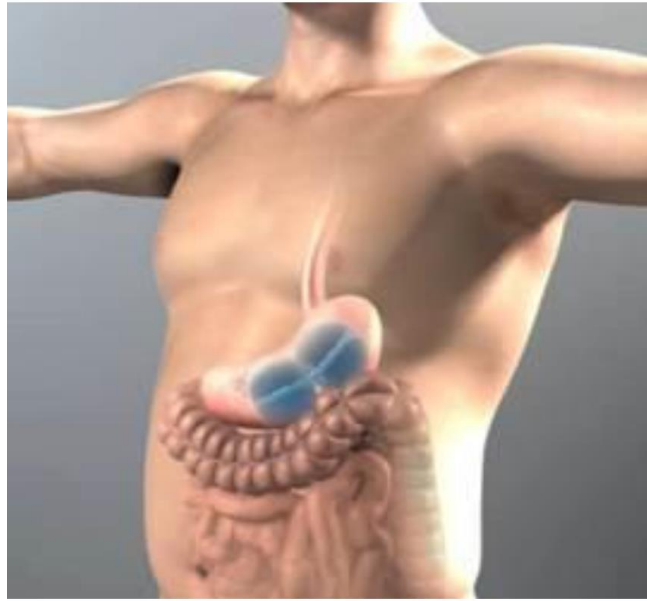


Figure 1. *ReShape* Dual Balloon in the Stomach

The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.

89. Lastly, claim 12 recites “wherein the obesity treatment device, upon at least partially filling the chambers, rests within the gastric cavity without exerting undue pressure against the gastric cavity at any particular point.” The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.

90. Claim 13 generally recites the method of claim 12, further comprising, after treating the obesity: (i) deflating, within the gastric cavity, each chamber of the plurality of inflatable space-filling chambers; and (ii) removing the obesity treatment device.

91. The Infringing Instrumentalities infringe claim 13 of the ‘915 patent. Regarding removal and deflation within the gastric cavity, the ReShape instructions state “continue aspiration until the proximal balloon is completely

1 deflated.” [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
2 content/uploads/2015/07/ReShape_Instructions_For_Use.pdf, at p. 18. ReShape
3 Dual Balloons are delivered through endoscopic procedures and “insertion and
4 removal may be completed in an endoscopy suite.” *See*
5 <http://pro.reshapeready.com/about-reshape/#theadvantages>.

6 92. Claim 14 generally recites the method of claim 13, wherein removing
7 the obesity treatment device comprises removing the obesity treatment device via
8 an esophagus of the patient.

9 93. The Infringing Instrumentalities infringe claim 14 of the ‘915 patent.
10 ReShape Dual Balloons are removed via endoscopic procedures and “insertion
11 and removal may be completed in an endoscopy suite.” *See*
12 <http://pro.reshapeready.com/about-reshape/#theadvantages>.

13 94. Claim 15 generally recites the method of claim 13, wherein deflating
14 each chamber comprises penetrating each chamber to release the fluid.

15 95. The Infringing Instrumentalities infringe claim 15 of the ‘915 patent.
16 The ReShape instructions state: “after retracting the needle, advance the catheter
17 through the cut hole until the balloon surface reaches the triple line marker on the
18 tubing” and “continue aspiration until the proximal balloon is completely
19 deflated.” [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
20 content/uploads/2015/07/ReShape_Instructions_For_Use.pdf, at p. 18. In other
21 words, deflating each chamber comprises penetrating each chamber to release the
22 fluid.

23 96. Claim 16 generally recites the method of claim 12, wherein
24 introducing the obesity treatment device inside the gastric cavity comprises
25 introducing the device though an esophagus of the patient.

26 97. The Infringing Instrumentalities infringe claim 16 of the ‘915 patent.
27 ReShape Dual Balloons are delivered through endoscopic procedures and
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1 “insertion and removal may be completed in an endoscopy suite.” *See*
2 <http://pro.reshapeready.com/about-reshape/#theadvantages>.

3 98. Claim 17 generally recites the method of claim 12, wherein, upon
4 inflation, the obesity treatment device rests within the gastric cavity without
5 exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

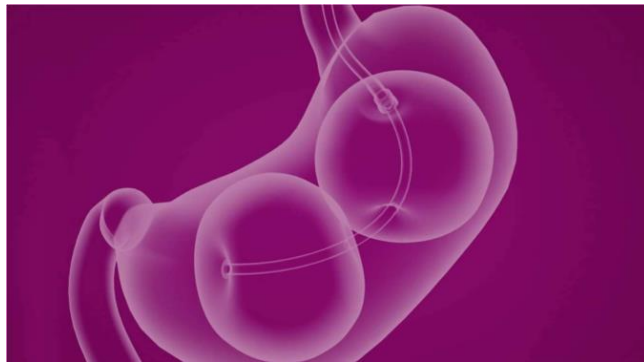
6 99. The Infringing Instrumentalities infringe claim 17 of the ‘915 patent.
7 The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual
8 gastric balloon is designed to conform to the patient’s anatomy and enhance
9 tolerability.” *See* <http://pro.reshapeready.com/about-reshape/#theadvantages>.
10 Accordingly, on information and belief, it is configured to rest within the gastric
11 cavity without exerting pressure at any point in the gastric cavity sufficient to
12 cause ulceration.

13 100. Claim 18 generally recites the method of claim 12, wherein at least
14 partially filling each chamber comprises: (i) releasably attaching an inflation tube
15 to the valve system; and (ii) introducing the fluid into a first chamber of the
16 plurality of inflatable space-filling chambers through the inflation tube.

17 101. The Infringing Instrumentalities infringe claim 18 of the ‘915 patent.
18 The chambers of the ReShape balloons are filled after they are positioned in the
19 patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for
20 Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
21 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The ReShape™
22 Valve Sealant is necessary to seal the device valves and prevent balloon leakage.”
23 *Id.* at 17. Accordingly, on information and belief, the ReShape balloons are filled
24 by releasably attaching an inflation tube to the valve system and introducing the
25 fluid into a first chamber of the inflatable space-filling chambers through the
26 inflation tube.

27 102. Claim 19 recites “an obesity treatment device for deploying in a
28 stomach of a patient, comprising: a means for occupying an overall space-filling

1 geometry having or conforming to a natural kidney shape of the stomach, upon
2 inflation, by aligning an outer surface of the obesity treatment device against
3 greater and lesser curvatures of the stomach” The Infringing
4 Instrumentalities infringe claim 19 of the ‘915 patent. The ReShape Dual Balloon
5 “is a temporary implant designed to facilitate weight loss by occupying space in
6 the stomach.” ReShape™ Integrated Dual Balloon System Instructions for Use,
7 PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
8 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The video on
9 ReShape’s website shows how the dual balloon structure conforms to the natural
10 curvature and shape of the stomach. <https://reshapeready.com/reshape-cc/>. A
11 frame from that video is reproduced below.



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19 The conformance of the dual balloon to the stomach of the patient is also
20 illustrated in Figure 1 of ReShape’s instructions for use, reproduced below.

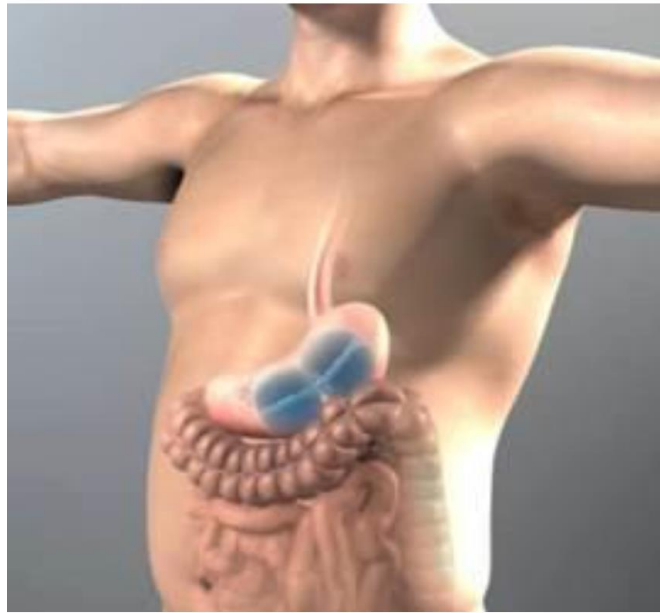


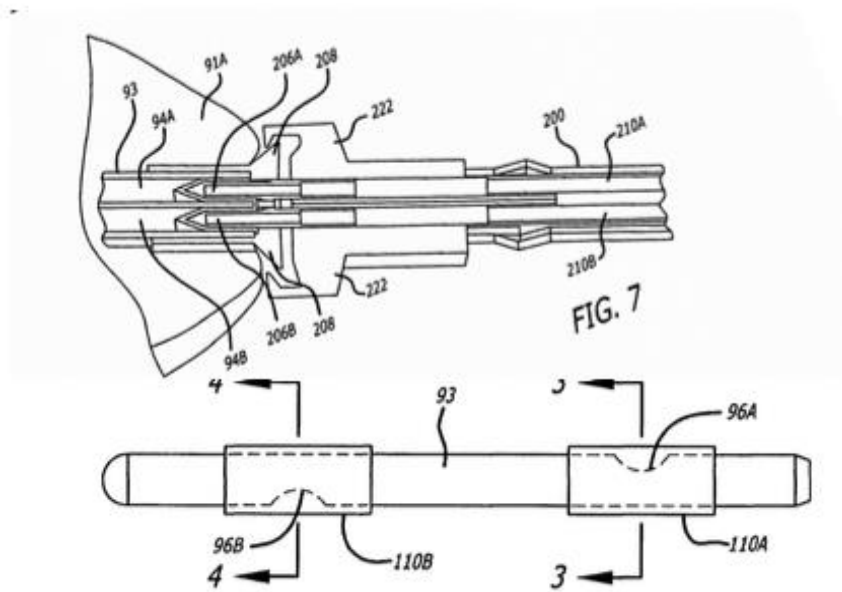
Figure 1. *ReShape* Dual Balloon in the Stomach

The *ReShape* Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.

103. Claim 19 further recites “a means for isolating a plurality of inflatable space-filling regions of the overall space-filling geometry such that a collective inflated state volume of the plurality of inflatable space-filling regions remaining inflated after deflation of any single region of the plurality of inflatable space-filling regions prevents the obesity treatment device from passing through a pyloric valve of the stomach” The introduction of the fluid to the balloons is described at pages 16-17 of the Instructions for Use, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. The *ReShape* website states that “[i]n the unlikely event of individual gastric balloon leakage or deflation, the independently sealed *ReShape* weight loss balloons are designed to minimize risk of migration or obstruction.” <http://pro.reshapeready.com/about-reshape/#theadvantages>. In other words, the dual balloon design will prevent the

1 implant from passing to the patient's intestinal tract in the event one of the
2 balloons ruptures or otherwise deflates.

3 104. Claim 19 further recites "a means for distributing a fluid to the
4 plurality of inflatable space-filling regions comprising a first means for receiving
5 a fluid into a first inflatable space-filling region of the plurality of inflatable
6 space-filling regions and for retaining the fluid in the first inflatable space-filling
7 region, and a second means for receiving the fluid into the first inflatable space-
8 filling region and for retaining the fluid in the first inflatable space-filling region,
9 wherein the first means is provided in series with the second means" The
10 chambers of the ReShape balloons are filled after they are positioned in the
11 patient's stomach. ReShape™ Integrated Dual Balloon System Instructions for
12 Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
13 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The ReShape dual
14 balloons are both filled with saline and remain at a fixed volume until they are
15 removed. *See* <https://www.youtube.com/watch?v=U91FsjtMf3o>;
16 [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
17 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p.
18 15-16. "The ReShape™ Valve Sealant is necessary to seal the device valves and
19 prevent balloon leakage." *Id.*; *see also*
20 <https://www.youtube.com/watch?v=U91FsjtMf3o>; Further, ReShape's patent,
21 U.S. 8,142,469, shows two valves in series as shown below at 206A and 96A:
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23
24
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105. Lastly, claim 19 recites “wherein a respective fluid volume for filling each region of the plurality of inflatable space-filling regions to occupy the overall space-filling geometry is selected based upon dimensions of the stomach of the patient.” Reshape’s instructions for use state as follows:

2.4. Determine the desired inflation volume for each balloon. A fill volume of 375 cc is recommended for patients < 64.5” in stature and 450 cc for patients ≥ 64.5” in stature.

See https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf at 16. ReShape instructs the user to determine the size of the patient and to select a corresponding fill volume for the balloon structure

106. Claim 20 generally recites the obesity treatment device of claim 19, further comprising a means for flexibly connecting at least the first inflatable space-filling region and a second inflatable space-filling region of the plurality of inflatable space-filling regions by spanning a gap between the first inflatable space-filling region and the second inflatable space-filling region, wherein the first inflatable space-filling region is configured to be spaced apart from the

1 second inflatable space-filling region within the stomach along a curved
2 longitudinal axis of the obesity treatment device.

3 107. The Infringing Instrumentalities infringe claim 20 of the '915 patent.
4 The ReShape dual balloons use a flexible spine to connect two gastric balloons.
5 The flexible central spine element is illustrated in the video provided on
6 ReShape's website, a frame from which is reproduced below. *See*
7 <https://reshapeready.com/reshape-cc/>; *see also*
8 <https://www.youtube.com/watch?v=U91FsjtMf3o>.

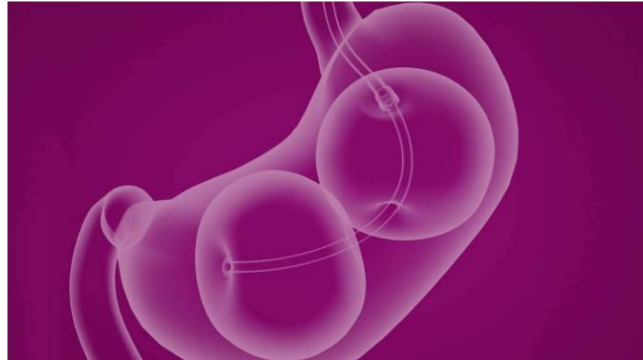


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16 Accordingly, upon information and belief, the ReShape spine flexibly
17 connects at least the first inflatable space-filling region and a second inflatable
18 space-filling region of the plurality of inflatable space-filling regions by spanning
19 a gap between the first inflatable space-filling region and the second inflatable
20 space-filling region, wherein the first inflatable space-filling region is configured
21 to be spaced apart from the second inflatable space-filling region within the
22 stomach along a curved longitudinal axis of the obesity treatment device.

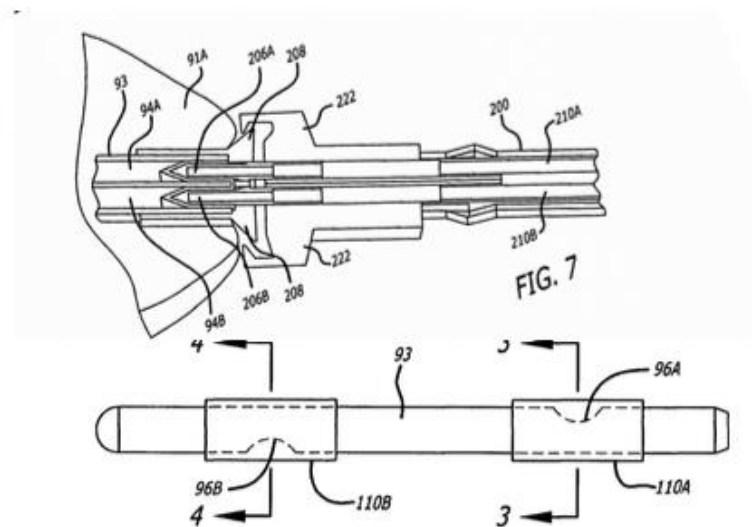
23 108. Claim 21 generally recites the obesity treatment device of claim 20,
24 wherein the means for flexibly connecting is in fluid communication with the
25 means for distributing the fluid.

26 109. Upon information and belief, the Infringing Instrumentalities infringe
27 claim 21 of the '915 patent. The flexible central spine element is illustrated in the
28 video provided on ReShape's website, a frame from which is reproduced below.

See <https://reshapeready.com/reshape-cc/>; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



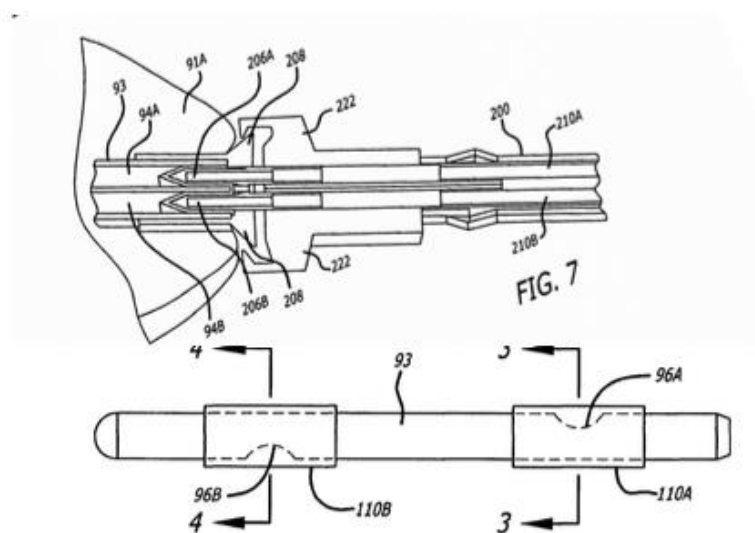
Accordingly, on information and belief, the ReShape balloon's flexible spine is in fluid communication with the means for distributing the fluid.

110. Claim 22 generally recites the obesity treatment device of claim 20, wherein the means for flexibly connecting is configured to detachably connect, after deploying in the stomach, to a means for introducing the fluid.

1 111. Upon information and belief, the Infringing Instrumentalities infringe
2 claim 22 of the '915 patent. The flexible central spine element is illustrated in the
3 video provided on ReShape's website, a frame from which is reproduced below.
4 See <https://reshapeready.com/reshape-cc/>; see also
5 <https://www.youtube.com/watch?v=U91FsjtMf3o>.



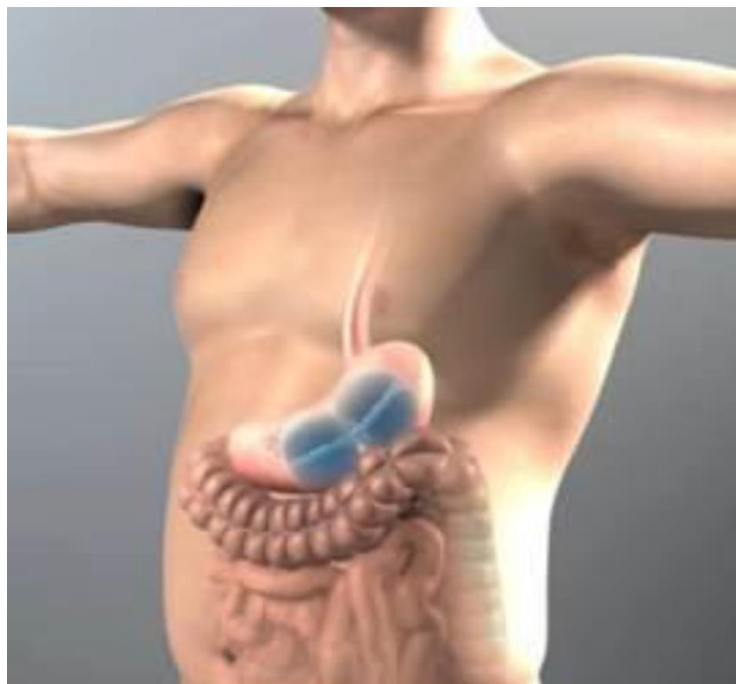
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11 Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and
12 valves are carried by the flexible central spine as shown below:



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23 Accordingly, on information and belief, the ReShape balloon's flexible
24 spine is configured to detachably connect, after deploying in the stomach, to a
25 means for introducing the fluid.

1 112. Claim 23 generally recites the obesity treatment device of claim 19,
2 wherein the means for occupying the overall space-filling geometry provides for
3 modulated passage of food through the stomach.

4 113. The Infringing Instrumentalities infringe claim 23 of the '915 patent.
5 The ReShape Dual Balloon "is a temporary implant designed to facilitate weight
6 loss by occupying space in the stomach." ReShape™ Integrated Dual Balloon
7 System Instructions for Use, PN 03-0300 Rev. D, p. 1,
8 [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
9 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below,
10 taken from ReShape's instruction manual, shows the dual balloon in a patient's
11 stomach providing modulated passage of food through the stomach.



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24 **Figure 1. ReShape Dual Balloon in the Stomach**

25 114. Claim 24 generally recites the obesity treatment device of claim 19,
26 wherein the means for occupying the overall space-filling geometry delineates a
27 space along a curved longitudinal axis of the obesity treatment device distal to the
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1 gastro-esophageal junction for the collection of ingested food and another space
2 proximal to the pyloric valve for active digestion.

3 115. The Infringing Instrumentalities infringe claim 24 of the '915 patent.
4 The images below from ReShape's website and instruction manual, found at
5 <https://reshapeready.com/reshape-cc/> and ReShape™ Integrated Dual Balloon
6 System Instructions for Use, PN 03-0300 Rev. D, p. 1,
7 [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
8 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), respectively,
9 demonstrate the geometry required to satisfy this element.

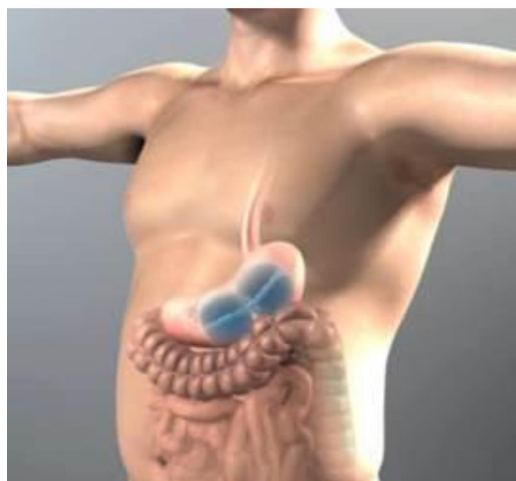


Figure 1. *ReShape* Dual Balloon in the Stomach

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25 Accordingly, on information and belief, the ReShape Balloon delineates a
26 space along a curved longitudinal axis of the obesity treatment device distal to the
27 gastro-esophageal junction for the collection of ingested food and another space
28 proximal to the pyloric valve for active digestion.

1 116. Claim 25 generally recites the obesity treatment device of claim 19,
2 wherein the means for occupying the overall space-filling geometry is configured
3 such that, upon inflation, the obesity treatment device rests within the gastric
4 cavity without exerting pressure at any point in the stomach sufficient to cause
5 ulceration.

6 117. The Infringing Instrumentalities infringe claim 25 of the ‘915 patent.
7 The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual
8 gastric balloon is designed to conform to the patient’s anatomy and enhance
9 tolerability.” *See* <http://pro.reshapeready.com/about-reshape/#theadvantages>.
10 Accordingly, on information and belief, it is configured to rest within the gastric
11 cavity without exerting pressure at any point in the gastric cavity sufficient to
12 cause ulceration.

13 118. Claim 26 generally recites the obesity treatment device of claim 19,
14 wherein the obesity treatment device is configured to be untethered in the stomach
15 after inflation.

16 119. The Infringing Instrumentalities infringe claim 26 of the ‘915 patent.
17 The following images below from ReShape’s website and instruction manual
18 demonstrate that a tether is not used in the ReShape Balloon System. *See*
19 *generally* <https://reshapeready.com/reshape-cc/>; ReShape™ Integrated Dual
20 Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1,
21 [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
22 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf).
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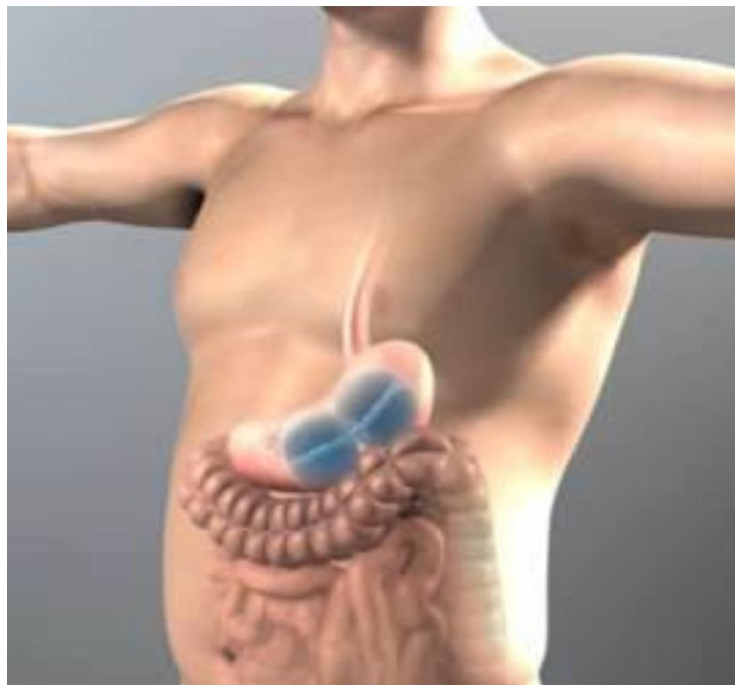
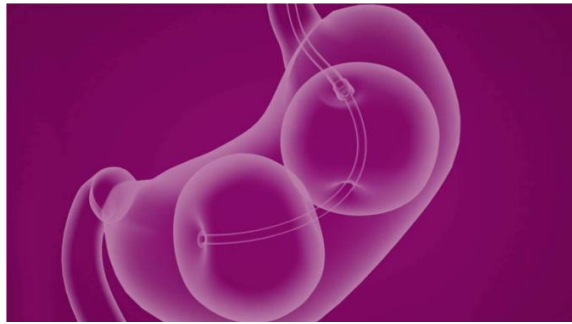


Figure 1. *ReShape* Dual Balloon in the Stomach

120. Claim 27 generally recites the obesity treatment device of claim 19, wherein the respective fluid volume of each region of the plurality of inflatable space-filling regions contains a same type of fluid.

121. The Infringing Instrumentalities infringe claim 27 of the '915 patent. The ReShape dual balloons are both filled with saline and remain at a fixed volume until they are removed. *See* <https://www.youtube.com/watch?v=U91FsjtMf3o>; https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf, Sec. 2.1 – 2.7 at p. 15-16.

1 122. On information and belief, the Infringing Instrumentalities are used
2 marketed, provided to, and/or used by or for each of ReShape Medical LLC and
3 ReShape Lifesciences's partners, clients, customers and end users across the
4 country and in this District.

5 123. ReShape Medical LLC and ReShape Lifesciences' infringement of
6 the '915 patent has been, and continues to be knowing, intentional, and willful, in
7 whole or in part because ReShape Medical, Inc. has been aware of the '915 patent
8 since its issuance and continue to engage in infringing conduct. ReShape
9 Medical, Inc. had knowledge of all major aspects of Fulfillium's business plans,
10 including trade secrets divulged pursuant to an oral agreement of confidentiality.
11 ReShape Medical, Inc. knew that Fulfillium was actively engaged in patenting its
12 gastric balloon technology. Further, ReShape Medical, Inc. was fully aware that
13 its technology would copy many aspects of Dr. Chen's inventions because it was
14 developed after and with knowledge of Dr. Chen's designs. The fact that
15 ReShape Medical, Inc. knew of Dr. Chen's patents and believed those patents to
16 be relevant to ReShape Medical, Inc.'s gastric balloon technology is demonstrated
17 by ReShape Medical Inc.'s citation of Dr. Chen's patents as relevant prior art
18 when attempting to procure its own patents. For instance, in December 2012
19 ReShape Medical, Inc. filed an information disclosure statement with the United
20 States Patent and Trademark Office indicating that Dr. Chen's previous patent
21 applications were relevant to ReShape Medical, Inc.'s pending patent application
22 directed to the ReShape Balloon. Further, outside of their inherited and/or
23 acquired liability from ReShape Medical, Inc. ReShape Lifesciences and ReShape
24 Medical LLC have been aware of the '915 patent since at least the time of the
25 merger, and any further infringement is willful.

26 124. On information and belief, each of ReShape Medical LLC and
27 ReShape Lifesciences has been aware of the existence of the '915 patent since its
28 issuance.

1 125. Upon information and belief, since at least the time each of ReShape
2 Medical LLC and ReShape Lifesciences has been made aware of the ‘915 patent,
3 each of ReShape Medical LLC and ReShape Lifesciences has induced and
4 continues to induce others to infringe at least one claim of the ‘915 patent under
5 35 U.S.C. § 271(b) by, among other things, and with specific intent or willful
6 blindness, actively aiding and abetting others to infringe, including but not limited
7 to each ReShape Medical LLC and ReShape Lifesciences’ partners, clients,
8 customers, and end users, whose use of the Infringing Instrumentalities constitutes
9 direct infringement of at least one claim of the ‘915 patent.

10 126. In particular, each of ReShape Medical LLC and ReShape
11 Lifesciences’ actions that aid and abet others such as its partners, customers,
12 clients, and end users to infringe include advertising and distributing the
13 Infringing Instrumentalities and providing instruction materials, training, and
14 services regarding the Infringing Instrumentalities. On information and belief,
15 each of ReShape Medical LLC and ReShape Lifesciences has engaged in such
16 actions with specific intent to cause infringement or with willful blindness to the
17 resulting infringement because each of ReShape Medical LLC and ReShape
18 Lifesciences has had actual knowledge of the ‘915 patent and knowledge that its
19 acts were inducing infringement of the ‘915 patent since at least the date each of
20 ReShape Medical LLC and ReShape Lifesciences received notice that such
21 activities infringed the ‘915 patent.

22 127. Upon information and belief, each of ReShape Medical LLC and
23 ReShape Lifesciences is liable as a contributory infringer of the ‘915 patent under
24 35 U.S.C. § 271(c) by offering to sell, selling and importing into the United States
25 gastric balloon technology to be especially made or adapted for use in an
26 infringement of the ‘915 patent. The Infringing Instrumentalities are a material
27 component for use in practicing the ‘915 patent and are specifically made and are
28 not a staple article of commerce suitable for substantial non-infringing use.

1 128. Fulfillium has suffered and will continue to suffer damages as a
2 result of ReShape Medical LLC and ReShape Lifesciences' infringing activities.
3 On information and belief, each of ReShape Medical LLC and ReShape
4 Lifesciences has been infringing, and will, unless enjoined by this Court, continue
5 to infringe the '915 patent by making, using, selling, offering to sell, and/or
6 importing, at a minimum, its ReShape Duo Balloon.

7 129. Each of ReShape Medical LLC and ReShape Lifesciences' acts of
8 infringement of the '915 patent have caused and will continue to cause Fulfillium
9 damages for which Fulfillium is entitled to compensation pursuant to 35 U.S.C. §
10 284.

11 130. Each of ReShape Medical LLC and ReShape Lifesciences' acts of
12 infringement of the '915 patent have caused and will continue to cause Fulfillium
13 immediate and irreparable harm unless such infringing activities are enjoined by
14 this Court pursuant to 35 U.S.C. § 283. Fulfillium has no adequate remedy at law.

15 131. This case is exceptional and, therefore, Fulfillium is entitled to an
16 award of attorneys' fees pursuant to 35 U.S.C. § 285.

17 **COUNT III – INFRINGEMENT OF U.S. PATENT NO. 9,445,930**

18 132. Fulfillium repeats the allegations of paragraphs 1-131 above as
19 though fully set forth herein.

20 133. On September 20, 2016, U.S. Patent No. 9,445,930 ("the '930
21 patent"), entitled "Methods, Devices, and Systems for Obesity Treatment," was
22 duly and legally issued by the United States Patent and Trademark Office. A true
23 and correct copy of the '930 patent is attached as Exhibit 2.

24 134. Fulfillium is the assignee and owner of the right, title and interest in
25 and to the '930 patent, including the right to assert all causes of action arising
26 under said patents and the right to any remedies for infringement of them by at
27 least an assignment dated July 16, 2018. (Ex. A.)
28

1 135. On information and belief, ReShape Medical LLC and ReShape
2 Lifesciences are engaged in the business of making, using, selling, offering to sell,
3 and/or importing medical devices. A description of ReShape Lifesciences’
4 business is available on its business website, which is located at
5 <http://pro.reshapeready.com>; <https://reshapeready.com/>.

6 136. As part of its business, each of ReShape Medical LLC and ReShape
7 Lifesciences makes, uses, offers to sell, sells, and/or imports a dual intragastric
8 balloon for weight loss, including ReShape Medical’s “Duo Balloon” device,
9 which is placed inside the patient’s stomach for weight loss. ReShape Medical
10 LLC and ReShape Lifesciences have purposefully sold and offered for sale such
11 Duo Balloon devices throughout the United States.

12 137. Upon information and belief, each of ReShape Medical LLC and
13 ReShape Lifesciences has and continues to directly infringe at least claims 1-2, 4-
14 19, 21-27, and 30 of the ‘930 patent by making, using, selling, importing and/or
15 providing and causing to be used medical devices for weight loss, including but
16 not limited to, those sold under the name ReShape Duo Balloon (the “Infringing
17 Instrumentalities”).

18 138. Claim 1 of the ‘930 patent generally recites “An obesity treatment
19 device for deploying in a stomach of a patient, comprising: a plurality of adjacent,
20 spaced apart inflatable space-filling compartments, wherein each compartment of
21 the plurality of inflatable space-filling compartments has a respective inflated state
22 volume that is maintained during treatment of the patient” The Infringing
23 Instrumentalities infringe claim 1 of the ‘930 patent. The ReShape Dual Balloon
24 “is a temporary implant designed to facilitate weight loss by occupying space in
25 the stomach.” ReShape™ Integrated Dual Balloon System Instructions for Use,
26 PN 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
27 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below,
28 taken from ReShape’s instruction manual, shows the dual balloon in a patient’s

1 stomach. The ReShape website states that “[i]n the unlikely event of individual
2 gastric balloon leakage or deflation, the independently sealed *ReShape* weight loss
3 balloons are designed to minimize risk of migration or obstruction.”

4 <http://pro.reshapeready.com/about-reshape/#theadvantages>. In other words, each
5 balloon inflates and deflates independently and its inflated volume is maintained.
6 *See also* <https://www.youtube.com/watch?v=U91FsjtMf3o>.

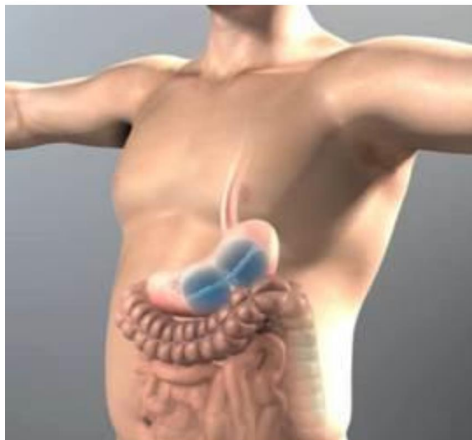
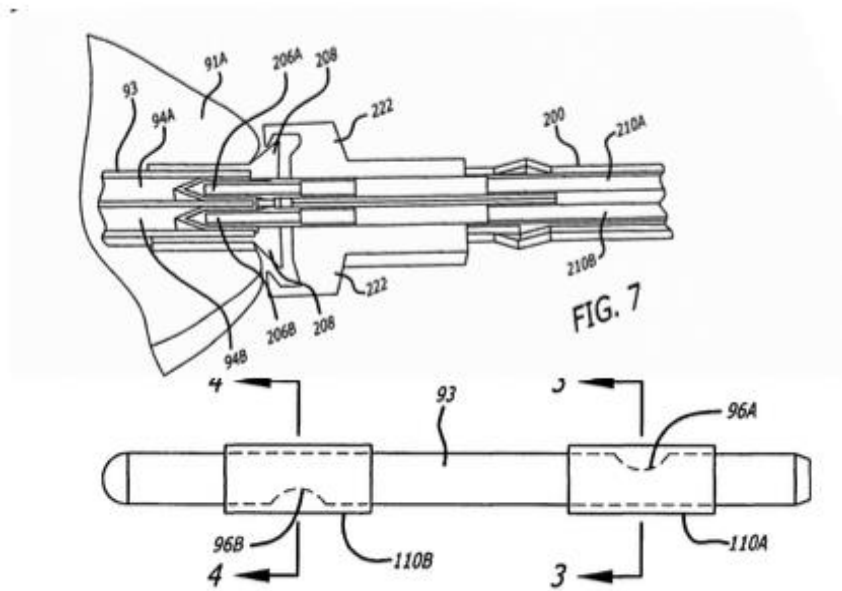


Figure 1. *ReShape* Dual Balloon in the Stomach

139. Claim 1 further recites “a valve system for introducing a fluid into
each compartment of the plurality of inflatable space-filling compartments and for
retaining, upon inflation, fluid in the plurality of inflatable space-filling
compartments” The chambers of the ReShape balloons are filled after they
are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon
System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17,
[https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. “The ReShape™
Valve Sealant is necessary to seal the device valves and prevent balloon leakage.”
Id.; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; U.S. Pat. No.
8,142,469 at Fig. 1, 3-5.

140. Claim 1 further recites “the valve system comprises a respective
valve structure for introducing fluid into each inflatable space-filling compartment

1 of the plurality of inflatable space-filling compartments, wherein each respective
2 valve structure includes at least a first valve in series with a second valve”
3 The chambers of the ReShape balloons are filled after they are positioned in the
4 patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for
5 Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
6 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The ReShape™
7 Valve Sealant is necessary to seal the device valves and prevent balloon leakage.”
8 *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; Further,
9 ReShape’s patent, U.S. 8,142,469, shows two valves in series as shown below at
10 206A and 96A:

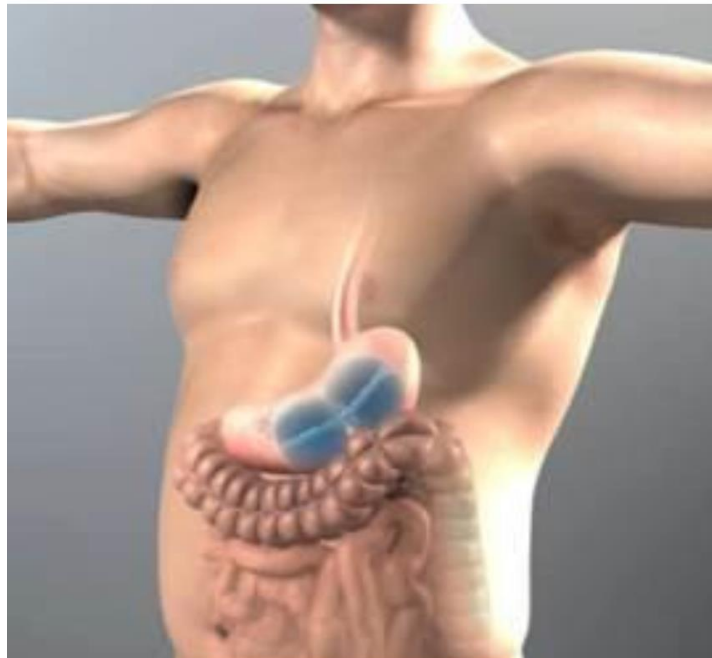


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23 141. Lastly, claim 1 recites “wherein the obesity treatment device is to
24 form, upon at least partially filling the plurality of inflatable space-filling
25 compartments, to a curved shape conforming to a natural three-dimensional
26 kidney shape of the stomach such that an outer surface of the obesity treatment
27 device aligns against greater and lesser curvatures of the stomach.” The video on
28 ReShape’s website shows how the dual balloon structure conforms to the natural

1 curvature of the stomach. <https://reshapeready.com/reshape-cc/>. A frame from
2 that video is reproduced below.



9 The conformance of the dual balloon to the stomach of the patient is also
10 illustrated in Figure 1 of ReShape’s instructions for use, reproduced below.



22 **Figure 1. *ReShape* Dual Balloon in the Stomach**

23
24 The ReShape Dual Balloon mimics “the natural curvature of the stomach,
25 the dual gastric balloon is designed to conform to the patient’s anatomy and
26 enhance tolerability.” See [http://pro.reshapeready.com/about-](http://pro.reshapeready.com/about-reshape/#theadvantages)
27 [reshape/#theadvantages](http://pro.reshapeready.com/about-reshape/#theadvantages).

142. Claim 2 generally recites the obesity treatment device of claim 1, wherein the plurality of inflatable space-filling compartments form, when in an inflated state, a cavity therebetween through which food may pass.

143. The Infringing Instrumentalities infringe claim 2 of the '930 patent. The ReShape Dual Balloon "is a temporary implant designed to facilitate weight loss by occupying space in the stomach." ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. The figure below, taken from ReShape's instruction manual, shows the dual balloon in a patient's stomach forming a cavity through which food may pass upon inflation.

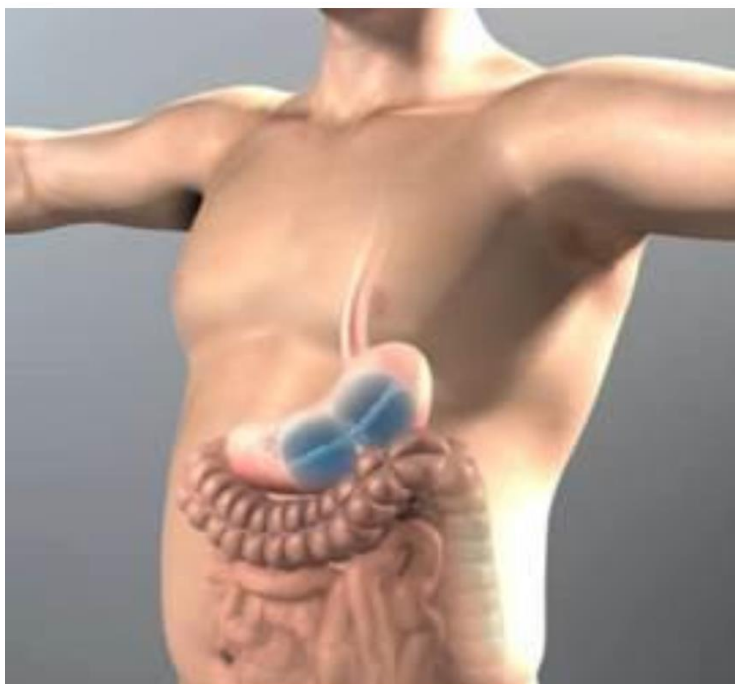


Figure 1. ReShape Dual Balloon in the Stomach

144. Claim 4 generally recites the obesity treatment device of claim 1, wherein, upon inflation, the obesity treatment device rests within the stomach without exerting pressure at any point in the stomach sufficient to cause ulceration.

1 145. The Infringing Instrumentalities infringe claim 4 of the ‘930 patent.
2 The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual
3 gastric balloon is designed to conform to the patient’s anatomy and enhance
4 tolerability.” *See* <http://pro.reshapeready.com/about-reshape/#theadvantages>.
5 Accordingly, on information and belief, it is configured to rest within the gastric
6 cavity without exerting pressure at any point in the gastric cavity sufficient to
7 cause ulceration.

8 146. Claim 5 generally recites the obesity treatment device of claim 1,
9 wherein an outer surface of each of the inflatable space-filling compartments
10 aligns against greater and lesser curvatures of the stomach.

11 147. The Infringing Instrumentalities infringe claim 5 of the ‘930 patent.
12 The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual
13 gastric balloon is designed to conform to the patient’s anatomy and enhance
14 tolerability.” *See* <http://pro.reshapeready.com/about-reshape/#theadvantages>.



21 The conformance of the dual balloon to the stomach of the patient is shown in the
22 image above and is also illustrated in Figure 1 of ReShape’s instructions for use,
23 reproduced below.

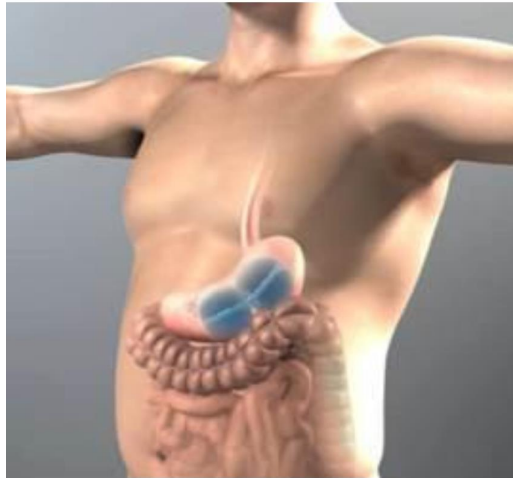


Figure 1. *ReShape* Dual Balloon in the Stomach

Accordingly, on information and belief, an outer surface of each of the inflatable space filling compartments is configured to align against greater and lesser curvatures of the stomach.

148. Claim 6 generally recites the obesity treatment device of claim 5, wherein the obesity treatment device is untethered in the stomach after inflation.

149. The Infringing Instrumentalities infringe claim 6 of the '930 patent. The following images below from ReShape's website and instruction manual demonstrate that the ReShape Balloon is untethered in the stomach after inflation. *See generally* <https://reshapeready.com/reshape-cc/>; ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf.



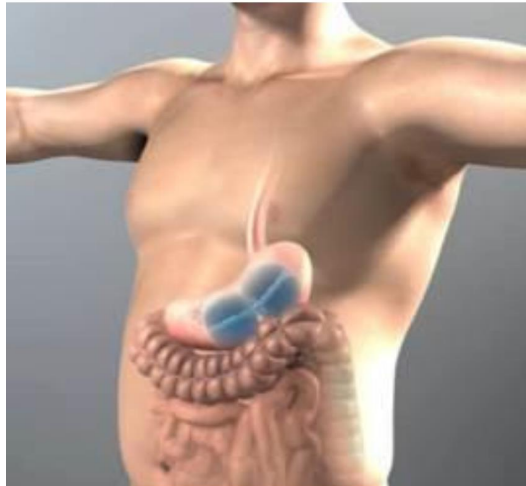
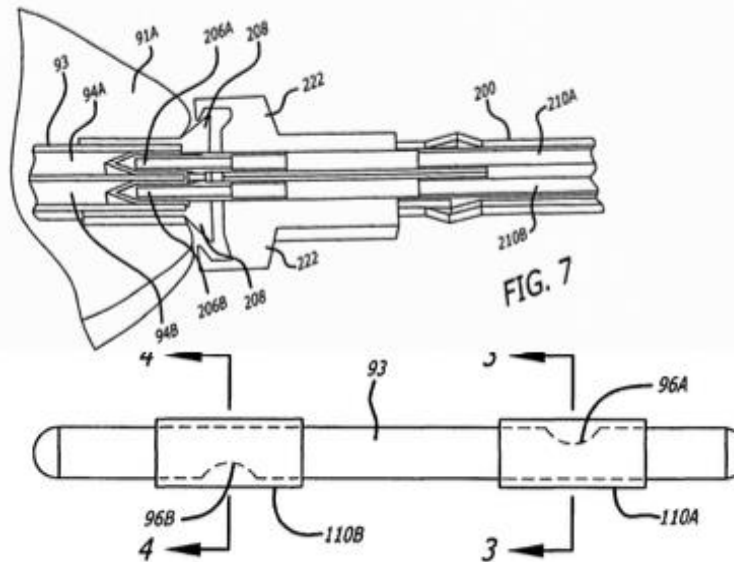


Figure 1. *ReShape* Dual Balloon in the Stomach

150. Claim 7 generally recites the obesity treatment device of claim 1, wherein the first valve structure includes a one-way valve.

151. Upon information and belief, the Infringing Instrumentalities infringe claim 7 of the '930 patent. The chambers of the ReShape balloons are filled after they are positioned in the patient's stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. "The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage." *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; Further, ReShape's patent, U.S. 8,142,469, shows a one-way valves as shown below at 206A and 96A:



Accordingly, on information and belief, the ReShape Balloon's first valve structure includes a one-way valve.

152. Claim 8 generally recites the obesity treatment device of claim 1, further comprising a flexible central spine structure spanning a gap between and connecting at least a first compartment of the plurality of inflatable space-filling compartments and a second compartment of the plurality of inflatable space-filling compartments, wherein aligning the outer surface of the obesity treatment device against the greater and lesser curvatures of the stomach comprises flexibly conforming the obesity treatment device to the natural three dimensional kidney shape of the stomach through flexing the flexible central spine structure.

153. The Infringing Instrumentalities infringe claim 8 of the '930 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See* <https://reshapeready.com/reshape-cc/>; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape's instructions for use, reproduced below.

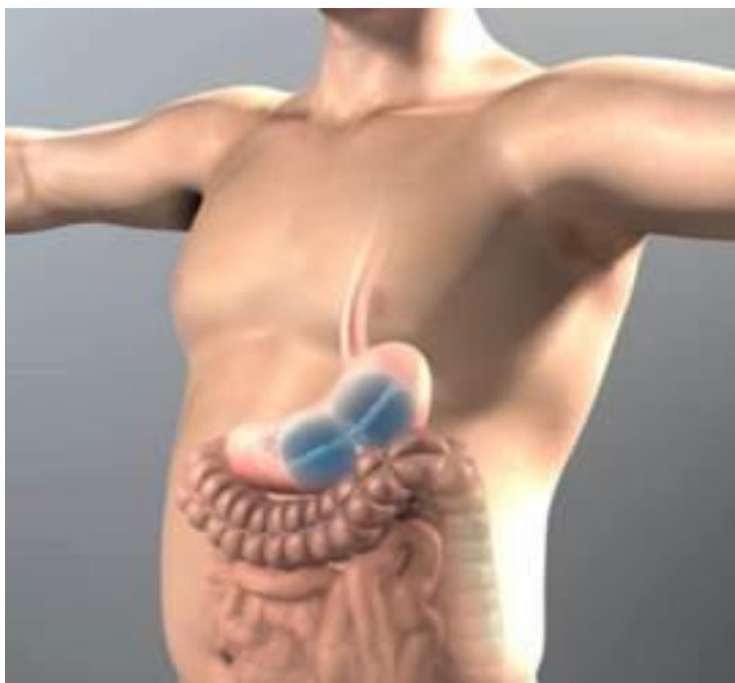


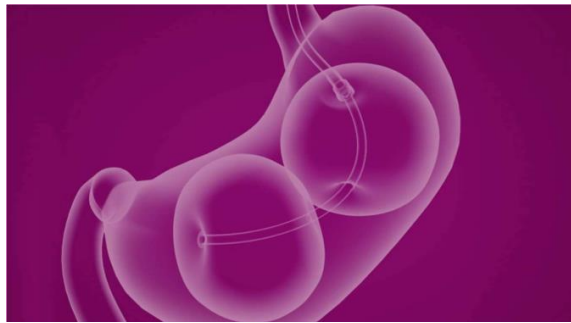
Figure 1. *ReShape* Dual Balloon in the Stomach

Accordingly, on information and belief, the ReShape Balloon's flexible central spine structure spans a gap between and connects at least a first compartment of the plurality of inflatable space-filling compartments and a second compartment of the plurality of inflatable space-filling compartments, wherein aligning the outer surface of the obesity treatment device against the greater and lesser curvatures of the stomach comprises flexibly conforming the

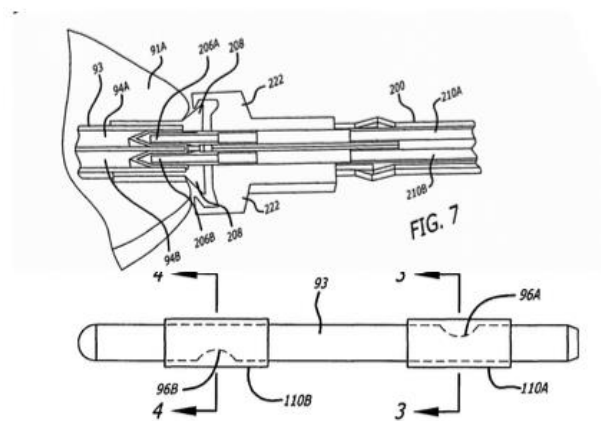
1 obesity treatment device to the natural three dimensional kidney shape of the
2 stomach through flexing the flexible central spine structure.

3 154. Claim 9 generally recites the obesity treatment device of claim 8,
4 wherein the flexible central spine structure is in fluid communication with the
5 valve system.

6 155. Upon information and belief, the Infringing Instrumentalities infringe
7 claim 9 of the '930 patent. The flexible central spine element is illustrated in the
8 video provided on ReShape's website, a frame from which is reproduced below.
9 See <https://reshapeready.com/reshape-cc/>; see also
10 <https://www.youtube.com/watch?v=U91FsjtMf3o>.



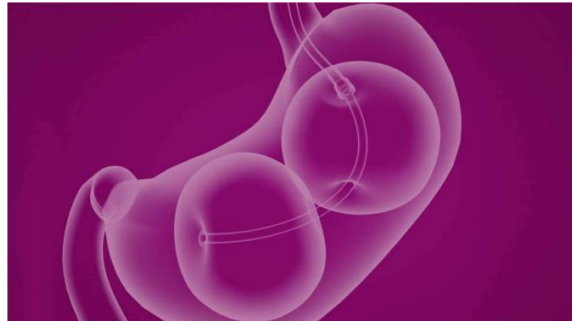
17 Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and
18 valves are carried by the flexible central spine as shown below:



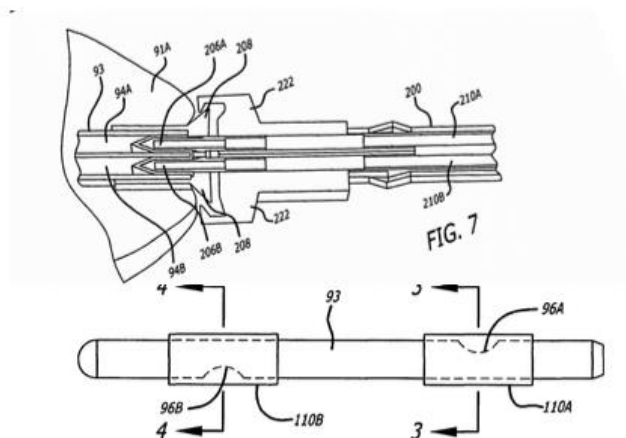
1 Accordingly, on information and belief, the ReShape Balloon's flexible
2 central spine structure is in fluid communication with the valve system.

3 156. Claim 10 generally recites the obesity treatment device of claim 9,
4 wherein the flexible central spine structure encloses an inflation lumen for
5 introducing the fluid into the plurality of inflatable space-filling compartments.

6 157. Upon information and belief, the Infringing Instrumentalities infringe
7 claim 10 of the '930 patent. The flexible central spine element is illustrated in the
8 video provided on ReShape's website, a frame from which is reproduced below.
9 See <https://reshapeready.com/reshape-cc/>; see also
10 <https://www.youtube.com/watch?v=U91FsjtMf3o>.



17 Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and
18 valves are carried by the flexible central spine as shown below:



1 Accordingly, on information and belief, the ReShape Balloon's flexible
2 central spine structure encloses an inflation lumen for introducing the fluid into
3 the plurality of inflatable space-filling compartments.

4 158. Claim 11 generally recites the obesity treatment device of claim 1,
5 wherein fluid in each of the plurality of inflatable space-filling compartments is a
6 same type of fluid.

7 159. The Infringing Instrumentalities infringe claim 11 of the '930 patent.
8 The ReShape dual balloons are both filled with saline and remain at a fixed
9 volume until they are removed. *See*
10 <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
11 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p.
12 15-16.

13 160. Claim 12 of the '930 patent recites a “method for deploying a gastric
14 balloon structure in a gastric cavity of a patient.” The ReShape Dual Balloon “is a
15 temporary implant designed to facilitate weight loss by occupying space in the
16 stomach.” ReShape™ Integrated Dual Balloon System Instructions for Use, PN
17 03-0300 Rev. D, p. 1, [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
18 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below,
19 taken from ReShape's instruction manual, shows the dual balloon in a patient's
20 stomach.
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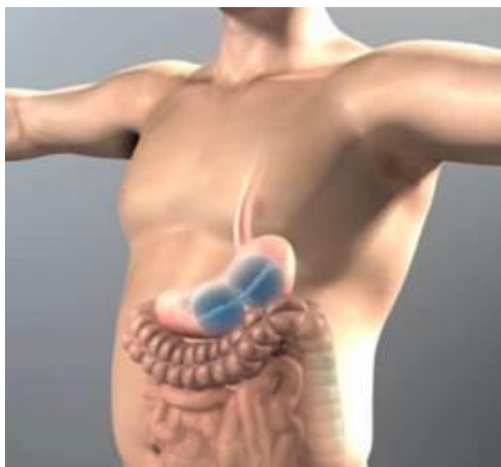


Figure 1. *ReShape* Dual Balloon in the Stomach

161. Claim 12 of the ‘930 patent further recites the steps of “determining one or more dimensions of the gastric cavity in a feeding state” and “selecting a respective fill volume for each chamber of a plurality of isolated chambers of the gastric balloon structure.” *Reshape*’s instructions for use state as follows:

2.4. Determine the desired inflation volume for each balloon. A fill volume of 375 cc is recommended for patients < 64.5” in stature and 450 cc for patients ≥ 64.5” in stature.

See [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)

[content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf) at 16. *ReShape* instructs the user to determine the size of the patient and to select a corresponding fill volume for the balloon structure.

162. Claim 12 further recites “introducing the gastric balloon structure to the gastric cavity; and after said introducing, at least partially filling each chamber of the plurality of isolated chambers of the gastric balloon structure with the respective volume of fluid via a valve system of the gastric balloon structure.”

The chambers of the *ReShape* balloons are filled after they are positioned in the patient’s stomach. *ReShape*TM Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. “The *ReShape*TM

1 Valve Sealant is necessary to seal the device valves and prevent balloon leakage.”
2 *Id.* at 17.

3 163. Claim 12 further recites that “the plurality of isolated chambers are
4 non-concentric and adjacent, at least partially filling each chamber of the plurality
5 of isolated chambers comprises introducing fluid into the respective chamber via a
6 respective valve structure of the valve system, and a collective volume of the
7 plurality of isolated chambers remaining inflated after deflation of any single
8 chamber of the plurality of isolated chambers prevents the gastric balloon
9 structure from passing through the pyloric valve of the gastric cavity.” Figure 1 of
10 the Instructions for Use shows that the ReShape balloon has two nonconcentric
11 and adjacent chambers. The introduction of the fluid to the balloons is described
12 at pages 16-17 of the Instructions for Use, [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
13 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf).. The ReShape
14 website states that “[i]n the unlikely event of individual gastric balloon leakage or
15 deflation, the independently sealed *ReShape* weight loss balloons are designed to
16 minimize risk of migration or obstruction.” [http://pro.reshapeready.com/about-](http://pro.reshapeready.com/about-reshape/#theadvantages)
17 [reshape/#theadvantages](http://pro.reshapeready.com/about-reshape/#theadvantages). In other words, the dual balloon design will prevent the
18 implant from passing to the patient’s intestinal tract in the event one of the
19 balloons ruptures.

20 164. Claim 12 further recites that “the gastric balloon structure, in its
21 inflated state, is to form to a curved shape conforming to a natural three-
22 dimensional kidney shape of the gastric cavity such that an outer surface of the
23 gastric balloon structure aligns against greater and lesser curvatures of the gastric
24 cavity.” The video on ReShape’s website shows how the dual balloon structure
25 conforms to the natural curvature of the stomach.
26 <https://reshapeready.com/reshape-cc/>. A frame from that video is reproduced
27 below.
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The conformance of the dual balloon to the stomach of the patient is also illustrated in Figure 1 of ReShape's instructions for use, reproduced below.

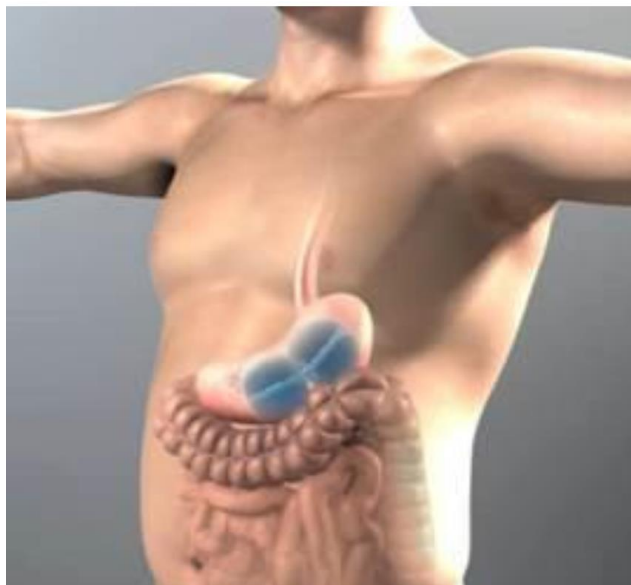


Figure 1. *ReShape* Dual Balloon in the Stomach

165. Claim 13 generally recites the method of claim 12, wherein the gastric balloon structure, upon inflation, rests within the gastric cavity without exerting pressure at any point in the gastric cavity sufficient to cause ulceration.

166. The Infringing Instrumentalities infringe claim 13 of the '930 patent. The ReShape Dual Balloon mimics "the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient's anatomy and enhance tolerability." See <http://pro.reshapeready.com/about-reshape/#theadvantages>. Accordingly, on information and belief, it is configured to rest within the gastric

1 cavity without exerting pressure at any point in the gastric cavity sufficient to
2 cause ulceration.

3 167. Claim 14 generally recites the method of claim 12, wherein an outer
4 surface of each one of the space-filling compartments aligns against greater and
5 lesser curvatures of the stomach.

6 168. The Infringing Instrumentalities infringe claim 14 of the '930 patent.
7 The ReShape Dual Balloon mimics "the natural curvature of the stomach, the dual
8 gastric balloon is designed to conform to the patient's anatomy and enhance
9 tolerability." See <http://pro.reshapeready.com/about-reshape/#theadvantages>.



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16 The conformance of the dual balloon to the stomach of the patient is shown in the
17 image above and is also illustrated in Figure 1 of ReShape's instructions for use,
18 reproduced below.

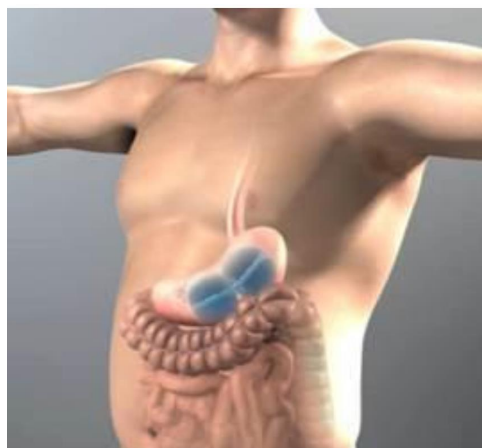


Figure 1. ReShape Dual Balloon in the Stomach

1 Accordingly, on information and belief, an outer surface of each of the
2 space filling compartments is configured to align against greater and lesser
3 curvatures of the gastric cavity.

4 169. Claim 15 generally recites the method of claim 12, wherein at least
5 partly filling the plurality of isolated chambers comprises (i) releasably attaching
6 an inflation tube to the valve system and (ii) introducing the fluid into a first
7 isolated chamber of the plurality of isolated chambers through the inflation tube.

8 170. The Infringing Instrumentalities infringe claim 15 of the ‘930 patent.
9 The chambers of the ReShape balloons are filled after they are positioned in the
10 patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for
11 Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
12 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The instructions
13 state: “Connect the inflation tubing to the proximal balloon fill tube (catheter
14 lanyard 1) and inflate to the desired volume. Monitor inflation under endoscopic
15 visualization.” *Id.* at 17. “The ReShape™ Valve Sealant is necessary to seal the
16 device valves and prevent balloon leakage.” *Id.* at 17. Accordingly, on
17 information and belief, the ReShape balloons are filled by releasibly attaching an
18 inflation tube to the valve system and introducing the fluid into a first chamber of
19 the inflatable space-filling chambers through the inflation tube.

20 171. Claim 16 generally recites the method of claim 12, wherein
21 introducing the gastric balloon structure to the gastric cavity comprises
22 introducing the gastric balloon structure through an esophagus of the patient.

23 172. The Infringing Instrumentalities infringe claim 16 of the ‘930 patent.
24 ReShape Dual Balloons are delivered through endoscopic procedures and
25 “insertion and removal may be completed in an endoscopy suite.” *See*
26 <http://pro.reshapeready.com/about-reshape/#theadvantages>.

1 173. Claim 17 generally recites the method of claim 12, wherein a
2 diameter of the gastric balloon structure is no larger than 2 centimeters prior to
3 inflation.

4 174. Upon information and belief, the Infringing Instrumentalities infringe
5 claim 17 of the ‘930 patent. *See* ReShape™ Integrated Dual Balloon System
6 Instructions for Use, PN 03-0300 Rev. D, pp. 2, 16-17,
7 [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
8 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf).

9 175. Claim 18 generally recites the method of claim 12, wherein fluid in
10 each of the plurality of isolated chambers is a same type of fluid.

11 176. The Infringing Instrumentalities infringe claim 18 of the ‘930 patent.
12 The ReShape dual balloons are both filled with saline and remain at a fixed
13 volume until they are removed. *See*
14 <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
15 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf), Sec. 2.1 – 2.7 at p.
16 15-16.

17 177. Claim 19 recites “a system for treating obesity, comprising: a means
18 for conforming a flexible, space-filling structure to a natural kidney shape of a
19 gastric cavity of a patient” The Infringing Instrumentalities infringe claim 19
20 of the ‘930 patent. The ReShape Dual Balloon “is a temporary implant designed
21 to facilitate weight loss by occupying space in the stomach.” ReShape™
22 Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1,
23 [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
24 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below,
25 taken from ReShape’s instruction manual, shows the dual balloon in a patient’s
26 stomach.

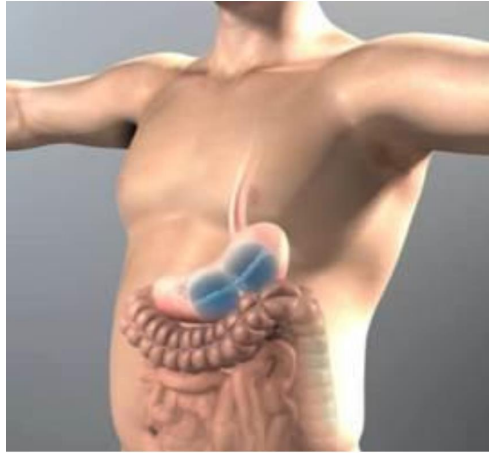


Figure 1. *ReShape* Dual Balloon in the Stomach

The *ReShape* Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>.

178. Claim 19 further recites “a means for maintaining at least two isolated inflatable regions of the flexible, space-filling structure such that a collective volume of the at least two isolated inflatable regions remaining inflated after deflation of any single isolated inflatable region of the at least two isolated inflatable regions prevents the flexible, space-filling structure from passing through the pylorus of the patient” Figure 1 of the Instructions for Use shows that the *ReShape* balloon has two nonconcentric and adjacent chambers. The introduction of the fluid to the balloons is described at pages 16-17 of the Instructions for Use, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. The *ReShape* website states that “[i]n the unlikely event of individual gastric balloon leakage or deflation, the independently sealed *ReShape* weight loss balloons are designed to minimize risk of migration or obstruction.” <http://pro.reshapeready.com/about-reshape/#theadvantages>. In other words, the dual balloon design will prevent the implant from passing to the patient’s intestinal tract in the event one of the balloons ruptures.

1 179. Claim 19 further recites “a means for introducing a fluid into each of
2 the at least two isolated inflatable regions after positioning the flexible, space-
3 filling structure within the gastric cavity, wherein the means for introducing is
4 configured to be separated from said means for conforming after introducing the
5 fluid” The chambers of the ReShape balloons are filled after they are
6 positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System
7 Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
8 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The ReShape™
9 Valve Sealant is necessary to seal the device valves and prevent balloon leakage.”
10 *Id.* at 17.

11 180. Lastly, claim 19 recites “a means for receiving the fluid into each
12 region of the at least two isolated inflatable regions and for retaining the fluid in
13 each region, wherein the fluid is received from the means for introducing the
14 fluid.” The chambers of the ReShape balloons are filled after they are positioned
15 in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions
16 for Use, PN 03-0300 Rev. D, pp. 16-17, [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
17 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). “The ReShape™
18 Valve Sealant is necessary to seal the device valves and prevent balloon leakage.”
19 *Id.* at 17.

20 181. Claim 21 generally recites the system of claim 19, wherein the means
21 for conforming provides for modulated passage of food through the gastric cavity.

22 182. The Infringing Instrumentalities infringe claim 21 of the ‘930 patent.
23 The ReShape Dual Balloon “is a temporary implant designed to facilitate weight
24 loss by occupying space in the stomach.” ReShape™ Integrated Dual Balloon
25 System Instructions for Use, PN 03-0300 Rev. D, p. 1,
26 [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
27 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). The figure below,
28

1 taken from ReShape's instruction manual, shows the dual balloon in a patient's
2 stomach providing modulated passage of food through the gastric cavity.

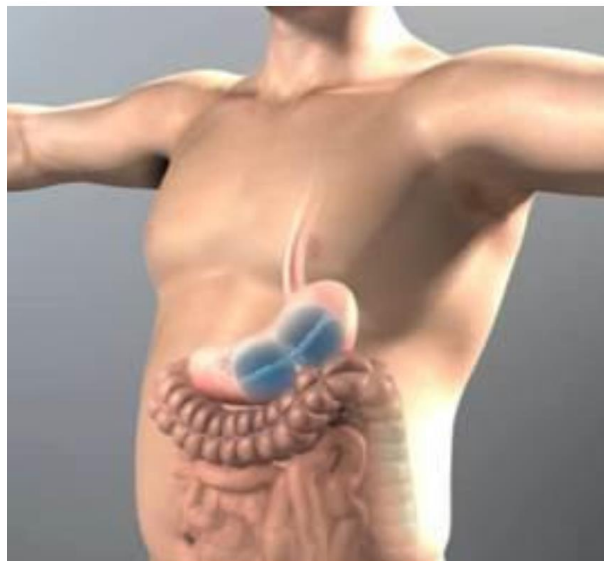


Figure 1. *ReShape* Dual Balloon in the Stomach

14 183. Claim 22 generally recites the system of claim 19, wherein the means
15 for conforming is configured such that, upon inflation, the flexible space-filling
16 structure rests within the gastric cavity without exerting pressure at any point in
17 the gastric cavity sufficient to cause ulceration.

18 184. The Infringing Instrumentalities infringe claim 22 of the '930 patent.
19 The ReShape Dual Balloon mimics "the natural curvature of the stomach, the dual
20 gastric balloon is designed to conform to the patient's anatomy and enhance
21 tolerability." See <http://pro.reshapeready.com/about-reshape/#theadvantages>.
22 Accordingly, on information and belief, it is configured to rest within the gastric
23 cavity without exerting pressure at any point in the gastric cavity sufficient to
24 cause ulceration.

25 185. Claim 23 generally recites the system of claim 22, wherein undue
26 pressure against the gastric cavity is avoided in part through at least one of i) a fill
27 weight of collective volumes of the at least two isolated inflatable regions, ii) a
28 distribution of the overall space-filling structure, and iii) a buoyancy of the fluid.

1 186. The Infringing Instrumentalities infringe claim 23 of the ‘930 patent.
2 The ReShape Balloon prevents undue pressure through a fill weight of collective
3 volumes of the at least two isolated inflatable regions. ReShape’s instructions for
4 use state as follows:

5 2.4. Determine the desired inflation volume for each balloon. A fill volume of
6 375 cc is recommended for patients < 64.5” in stature and 450 cc for patients ≥
7 64.5” in stature.

8 *See* [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
9 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf) at 16. ReShape
10 instructs the user to determine the size of the patient and to select a corresponding
11 fill volume for the balloon structure. Further, the ReShape Dual Balloon prevents
12 undue pressure through a distribution of the overall space-filling structure in that it
13 mimics “the natural curvature of the stomach, the dual gastric balloon is designed
14 to conform to the patient’s anatomy and enhance tolerability.” *See*
15 <http://pro.reshapeready.com/about-reshape/#theadvantages>.

16 187. Claim 24 generally recites the system of claim 19, wherein the means
17 for receiving the fluid comprises a respective valve structure of each region of the
18 at least two isolated inflatable regions, the respective valve structure comprising at
19 least a first valve and a second valve.

20 188. Upon information and belief, the Infringing Instrumentalities infringe
21 claim 24 of the ‘930 patent. The chambers of the ReShape balloons are filled after
22 they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon
23 System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17,
24 [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
25 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf). Each of the two
26 balloons in the ReShape Balloon are filled through a valve system as
27 demonstrated by the instructional videos and instruction manual, which states
28 “[t]he ReShape™ Valve Sealant is necessary to seal the device valves and prevent

balloon leakage.” *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; <http://pro.reshapeready.com/about-reshape/> (providing an in-patient medical instructional video about placement, inflation, and removal of the ReShape Balloon). Accordingly, on information and belief, the ReShape Balloon valves comprise a respective valve structure of each region of the at least two isolated inflatable regions, the respective valve structure comprising at least a first valve and a second valve.

189. Claim 25 generally recites the system of claim 19, further comprising a means for flexibly connecting at least a first region of the at least two isolated inflatable regions and a second region of the at least two isolated inflatable regions by spanning a gap between the first region and the second region, thereby forming a cavity between the first region and the second region through which food may pass.

190. The Infringing Instrumentalities infringe claim 25 of the ‘930 patent. The flexible central spine element is illustrated in the video provided on ReShape’s website, a frame from which is reproduced below. *See* <https://reshapeready.com/reshape-cc/>; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape’s instructions for use, reproduced below.

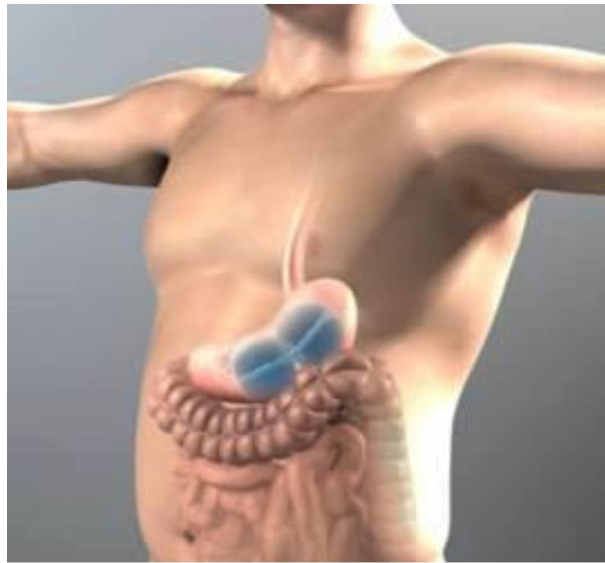


Figure 1. *ReShape* Dual Balloon in the Stomach

Accordingly, on information and belief, the ReShape Balloon's spine flexibly connects at least a first region of the at least two isolated inflatable regions and a second region of the at least two isolated inflatable regions by spanning a gap between the first region and the second region, thereby forming a cavity between the first region and the second region through which food may pass.

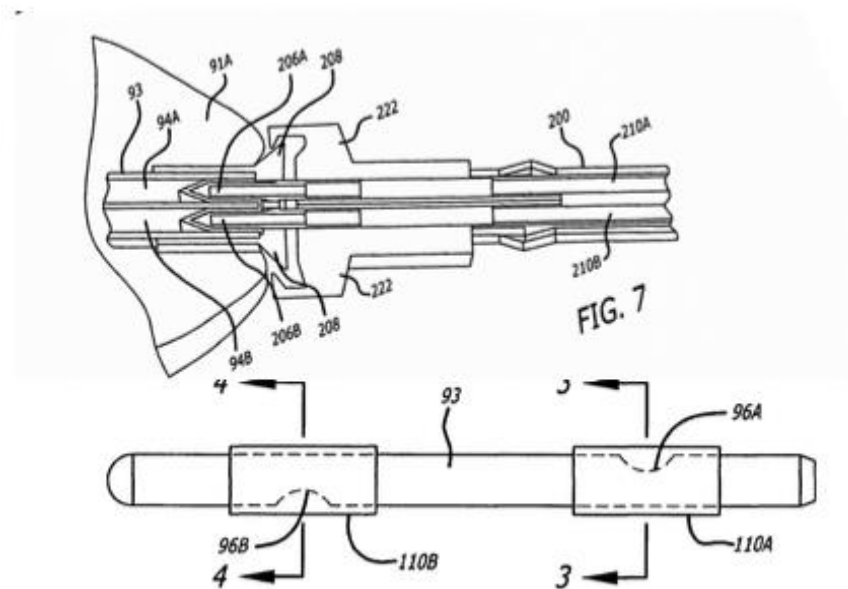
191. Claim 26 generally recites the system of claim 25, wherein the means for flexibly connecting at least the first isolated inflatable region and the second isolated inflatable region is in fluid communication with the means for receiving the fluid.

192. Upon information and belief, the Infringing Instrumentalities infringe claim 26 of the '930 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below.

See <https://reshapeready.com/reshape-cc/>; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



Accordingly, on information and belief, the ReShape Balloon's spine is in fluid communication with the means for receiving the fluid.

193. Claim 27 generally recites the system of claim 25, wherein the means for flexibly connecting comprises a flexible central spine.

194. The Infringing Instrumentalities infringe claim 27 of the '930 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. See <https://reshapeready.com/reshape-cc/>; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape's instructions for use, reproduced below.

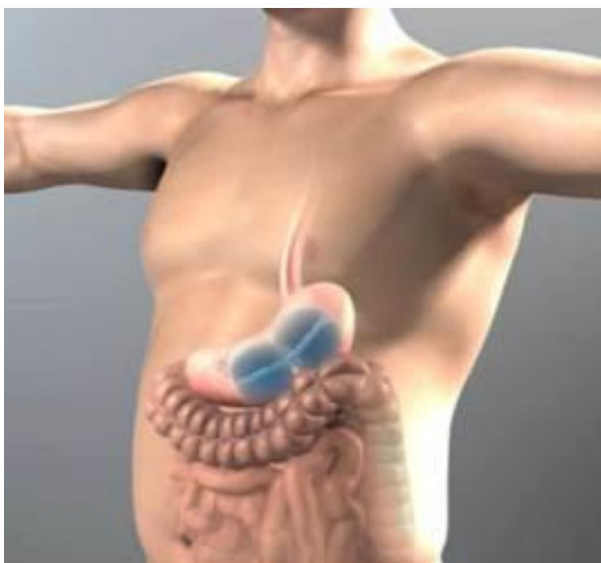


Figure 1. *ReShape* Dual Balloon in the Stomach

195. Claim 30 generally recites the system of claim 19, wherein fluid in each of the at least two isolated inflatable regions is a same type of fluid.

196. The Infringing Instrumentalities infringe claim 30 of the '930 patent. The ReShape dual balloons are both filled with saline and remain at a fixed volume until they are removed. *See* <https://www.youtube.com/watch?v=U91FsjtMf3o>; https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf, Sec. 2.1 – 2.7 at p. 15-16.

1 197. On information and belief, the Infringing Instrumentalities are used
2 marketed, provided to, and/or used by or for each of ReShape Medical LLC and
3 ReShape Lifesciences' partners, clients, customers and end users across the
4 country and in this District.

5 198. On information and belief, each of ReShape Medical LLC and
6 ReShape Lifesciences has been aware of the existence of the '930 patent since its
7 issuance.

8 199. On information and belief, since at least the time each of ReShape
9 Medical LLC and ReShape Lifesciences has been aware of the '930 patent, it has
10 induced and continues to induce others to infringe at least one claim of the '930
11 patent under 35 U.S.C. § 271(b) by, among other things, and with specific intent
12 or willful blindness, actively aiding and abetting others to infringe, including but
13 not limited to each of ReShape Medical LLC and ReShape Lifesciences' partners,
14 clients, customers, and end users, whose use of the ReShape Medical Duo Balloon
15 constitutes direct infringement of at least one claim of the '930 patent.

16 200. In particular, each of ReShape Medical LLC and ReShape
17 Lifesciences' actions that aid and abet others such as its partners, customers,
18 clients, and end users to infringe include advertising and distributing the ReShape
19 Medical Duo Balloon, and providing instruction materials, training, and services
20 regarding the ReShape Medical Duo Balloon. On information and belief, each of
21 ReShape Medical LLC and ReShape Lifesciences has engaged in such actions
22 with specific intent to cause infringement or with willful blindness to the resulting
23 infringement because, on information and belief, it has had actual knowledge of
24 the '930 patent and knowledge that its acts were inducing infringement of the '930
25 patent since at least the date the '930 patent issued.

26 201. Upon information and belief, each of ReShape Medical LLC and
27 ReShape Lifesciences is liable as a contributory infringer of the '930 patent under
28 35 U.S.C. § 271(c) by offering to sell, selling and importing into the United States

1 gastric balloon technology to be especially made or adapted for use in an
2 infringement of the '930 patent. The Infringing Instrumentalities are a material
3 component for use in practicing the '930 patent and are specifically made and are
4 not a staple article of commerce suitable for substantial non-infringing use.

5 202. ReShape Medical LLC and ReShape Lifesciences' infringement of
6 the '930 patent has been, and continues to be knowing, intentional, and willful, in
7 whole or in part because ReShape Medical, Inc. has been aware of the '930 patent
8 since its issuance and continue to engage in infringing conduct. ReShape
9 Medical, Inc. had knowledge of all major aspects of Fulfillium's business plans,
10 including trade secrets divulged pursuant to an oral agreement of confidentiality.
11 ReShape Medical, Inc. knew that Fulfillium was actively engaged in patenting its
12 gastric balloon technology. Further, ReShape Medical, Inc. was fully aware that
13 its technology would copy many aspects of Dr. Chen's inventions because it was
14 developed after and with knowledge of Dr. Chen's designs. The fact that
15 ReShape Medical, Inc. knew of Dr. Chen's patents and believed those patents to
16 be relevant to ReShape Medical, Inc.'s gastric balloon technology is demonstrated
17 by ReShape Medical, Inc.'s citation of Dr. Chen's patents as relevant prior art
18 when attempting to procure its own patents. For instance, in December 2012
19 ReShape Medical, Inc. filed an information disclosure statement with the United
20 States Patent and Trademark Office indicating that Dr. Chen's previous patent
21 applications were relevant to ReShape Medical, Inc.'s pending patent application
22 directed to the ReShape Balloon. Further, outside of their inherited and/or
23 acquired liability from ReShape Medical, Inc., ReShape Lifesciences and
24 ReShape LLC have been aware of the '930 patent since at least the time of the
25 merger, and any further infringement is willful.

26 203. Each of ReShape Medical LLC and ReShape Lifesciences' acts of
27 infringement of the '930 patent have caused and will continue to cause Fulfillium
28

1 damages for which Fulfillium is entitled to compensation pursuant to 35 U.S.C. §
2 284.

3 204. Each of ReShape Medical LLC and ReShape Lifesciences' acts of
4 infringement of the '930 patent have caused and will continue to cause Fulfillium
5 immediate and irreparable harm unless such infringing activities are enjoined by
6 this Court pursuant to 35 U.S.C. § 283. Fulfillium has no adequate remedy at law.

7 205. This case is exceptional and, therefore, Fulfillium is entitled to an
8 award of attorneys' fees pursuant to 35 U.S.C. § 285.

9 **COUNT IV – INFRINGEMENT OF U.S. PATENT NO. 9,808,367**

10 206. Fulfillium repeats the allegations of paragraphs 1-205 above as
11 though fully set forth herein.

12 207. On November 7, 2017, U.S. Patent No. 9,808,367 ("the '367
13 patent"), entitled "Methods, Devices, and Systems for Obesity Treatment," was
14 duly and legally issued by the United States Patent and Trademark Office. A true
15 and correct copy of the '367 patent is attached as Exhibit 4.

16 208. Fulfillium is the assignee and owner of the right, title and interest in
17 and to the '367 patent, including the right to assert all causes of action arising
18 under said patents and the right to any remedies for infringement of them by at
19 least an assignment dated July 16, 2018. (Ex. A.)

20 209. On information and belief, each of ReShape Medical LLC and
21 ReShape Lifesciences is engaged in the business of making, using, selling,
22 offering to sell, and/or importing medical devices. A description of ReShape
23 Lifesciences' business is available on its business website, which is located at
24 <http://pro.reshapeready.com>; <https://reshapeready.com/>.

25 210. As part of its business, each of ReShape Medical LLC and ReShape
26 Lifesciences makes, uses, offers to sell, sells, and/or imports a dual intragastric
27 balloon for weight loss, including ReShape Medical's "Duo Balloon" device,
28 which is placed inside the patient's stomach for weight loss. ReShape Medical

1 LLC and ReShape Lifesciences have purposefully sold and offered for sale such
2 Duo Balloon devices throughout the United States.

3 211. Upon information and belief, each of ReShape Medical LLC and
4 ReShape Lifesciences has and continues to directly infringe at least claims 1-2, 4-
5 7, 11-12, and 16-21 of the ‘367 patent by making, using, selling, importing and/or
6 providing and causing to be used medical devices for weight loss, including but
7 not limited to, those sold under the name ReShape Duo Balloon (the “Infringing
8 Instrumentalities”).

9 212. Representative claim 1 of the ‘367 patent recites a “free floating,
10 untethered gastric balloon structure for deploying in a gastric cavity of a patient,
11 comprising: at least two isolated non-concentric inflatable chambers, wherein each
12 chamber of the at least two isolated non-concentric inflatable chambers has a
13 respective inflated state volume such that deflation of any single chamber of the at
14 least two isolated non-concentric inflatable chambers leaves the inflated state
15 volume of the remaining chambers of the at least two isolated non-concentric
16 inflatable chambers unaffected[.]” The Infringing Instrumentalities infringe claim
17 1 of the ‘367 patent. The ReShape Dual Balloon “is a temporary implant designed
18 to facilitate weight loss by occupying space in the stomach.” ReShape™
19 Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1,
20 [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
21 [content/uploads/2015/07/ReShape_Instructions_For_Use.pdf](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf); *see also*
22 <https://reshapeready.com/reshape-cc/>. The figures below, taken from ReShape’s
23 instruction manual and documentation, show the dual balloon untethered in a
24 patient’s stomach. The ReShape website states that “[i]n the unlikely event of
25 individual gastric balloon leakage or deflation, the independently sealed *ReShape*
26 weight loss balloons are designed to minimize risk of migration or obstruction.”
27 <http://pro.reshapeready.com/about-reshape/#theadvantages>. In other words, each
28

balloon inflates and deflates independently. *See also* <https://www.youtube.com/watch?v=U91FsjtMf3o>.

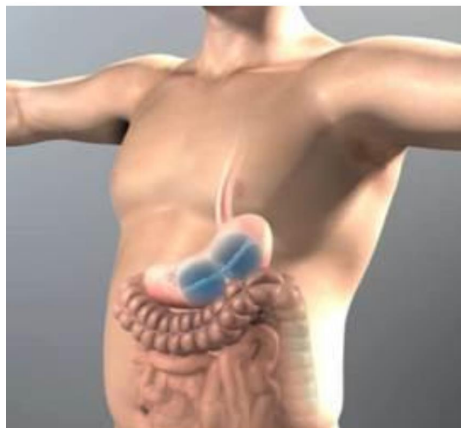
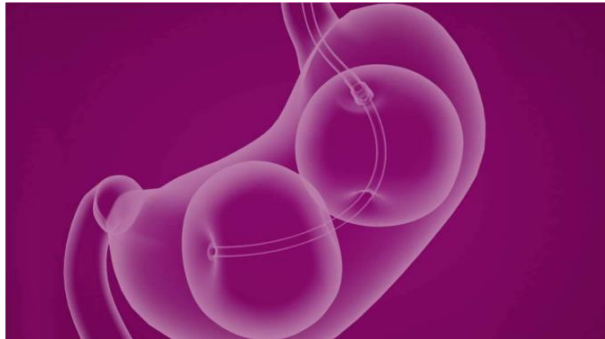


Figure 1. ReShape Dual Balloon in the Stomach

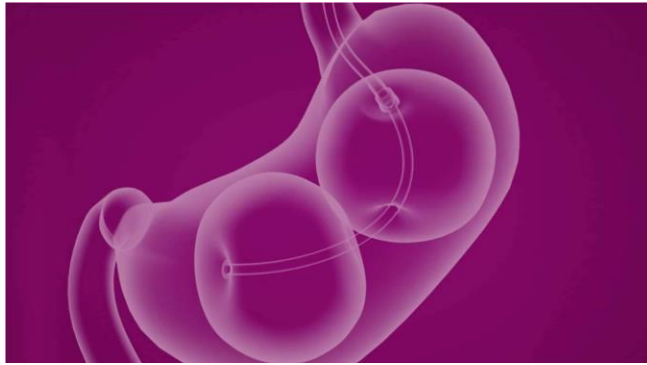
213. Claim 1 further recites “a valve system for introducing a fluid into the at least two isolated non-concentric inflatable chambers and for retaining, upon inflation, the fluid in the at least two isolated non-concentric inflatable chambers.” The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; U.S. Pat. No. 8,142,469 at Fig. 1, 3-5.

214. Claim 1 further recites “a flexible member spanning a gap between and fixedly attached to both a first chamber of the at least two isolated non-

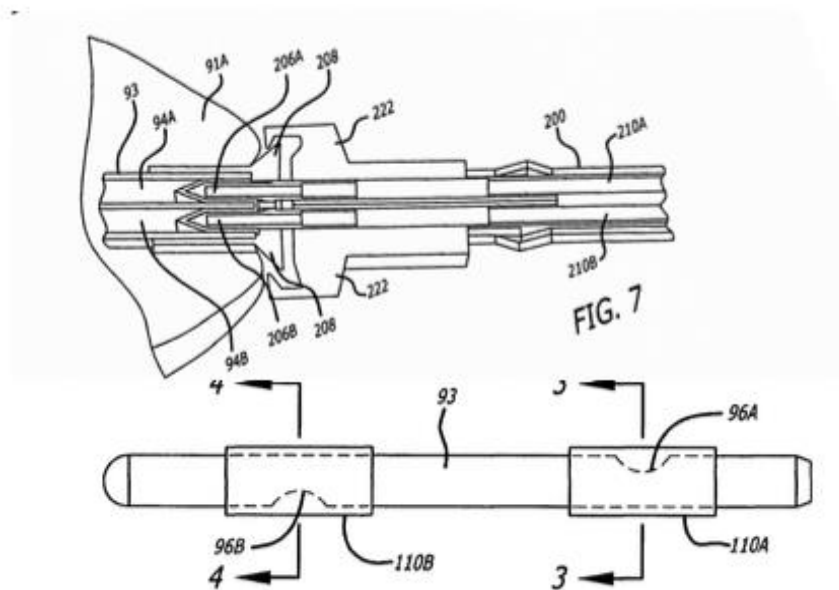
1 concentric inflatable chambers and a second chamber of the at least two isolated
2 non-concentric inflatable chambers, said flexible member carrying inflation tubes
3 that are in fluid communication with the at least two isolated non-concentric
4 inflatable chambers; wherein the gastric balloon structure is configured to float
5 freely in the patient's gastric cavity and is not connected to any catheter, lumen or
6 tether after deployment in the patient's gastric cavity[.]” The flexible member
7 element is illustrated in the video provided on ReShape's website, a frame from
8 which is reproduced below. *See* <https://reshapeready.com/reshape-cc/>; *see also*
9 <https://www.youtube.com/watch?v=U91FsjtMf3o>.



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17 Upon information and belief, the flexible member of the dual balloon carries
18 inflation tubes that are in fluid communication with the two isolated non-
19 concentric inflatable chambers. The flexible member element is illustrated in the
20 video provided on ReShape's website, a frame from which is reproduced below.
21 *See* <https://reshapeready.com/reshape-cc/>; *see also*
22 <https://www.youtube.com/watch?v=U91FsjtMf3o>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible member as shown below:



Accordingly, on information and belief, the ReShape balloon's flexible member is in fluid communication with the means for distributing the fluid. The following images below from ReShape's website and instruction manual demonstrate that a tether is not used in the ReShape Balloon System. *See generally* <https://reshapeready.com/reshape-cc/>; ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf.

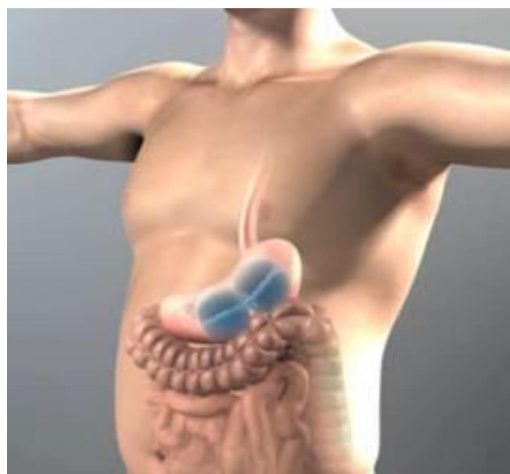


Figure 1. *ReShape* Dual Balloon in the Stomach

215. The final recitation in claim 1 recites “wherein the gastric balloon structure, in its inflated state, assumes a curved shape conforming to a natural three dimensional kidney shape of the gastric cavity, such that the flexible member flexibly conforms, upon at least partially filling the at least two isolated non-concentric inflatable chambers, the gastric balloon structure to the natural three-dimensional kidney shape of the gastric cavity.” The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of *ReShape*’s instructions for use, reproduced below.

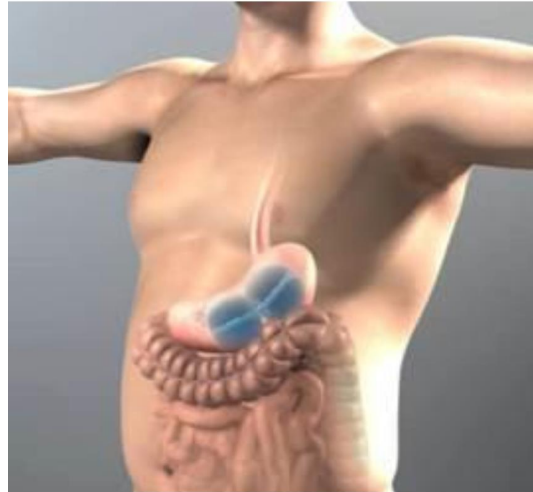


Figure 1. *ReShape* Dual Balloon in the Stomach

216. Claim 2 generally recites the gastric balloon structure of claim 1, wherein the gastric balloon structure is configured to provide for modulated passage of food through the gastric cavity upon inflation.

217. The Infringing Instrumentalities infringe claim 2 of the ‘367 patent. The ReShape Dual Balloon “is a temporary implant designed to facilitate weight loss by occupying space in the stomach.” ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. The figure below, taken from ReShape’s instruction manual, shows the dual balloon in a patient’s stomach providing modulated passage of food through the gastric cavity upon inflation.

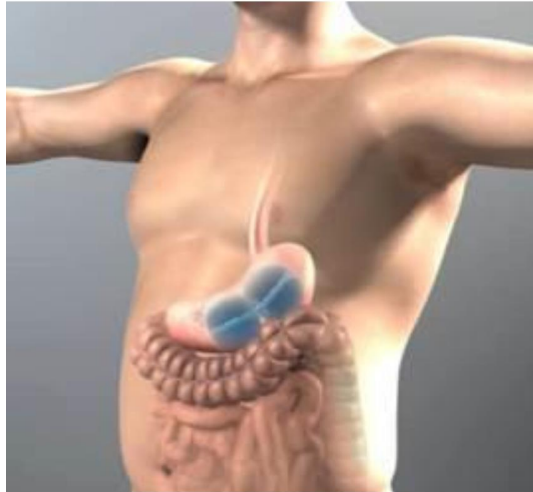


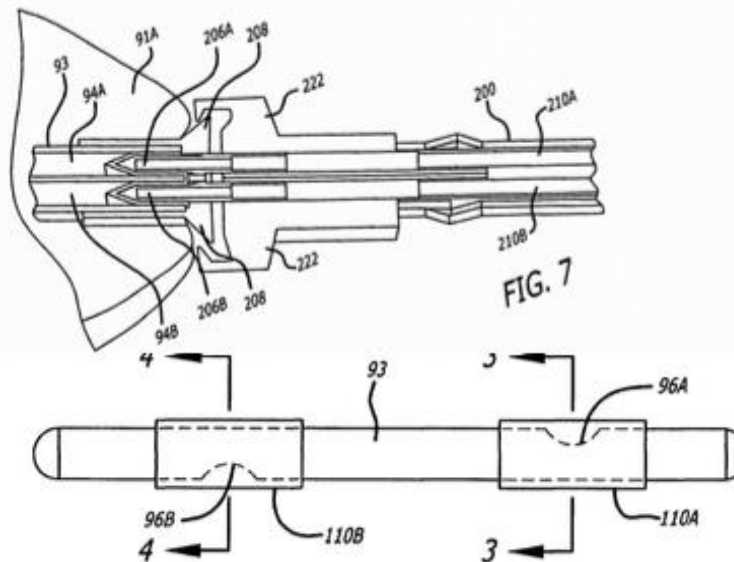
Figure 1. *ReShape* Dual Balloon in the Stomach

218. Claim 4 generally recites the gastric balloon structure of claim 1, wherein the flexible member is in fluid communication with the valve system.

219. Upon information and belief, the Infringing Instrumentalities infringe claim 4 of the '367 patent. The flexible member element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See* <https://reshapeready.com/reshape-cc/>; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible member as shown below:



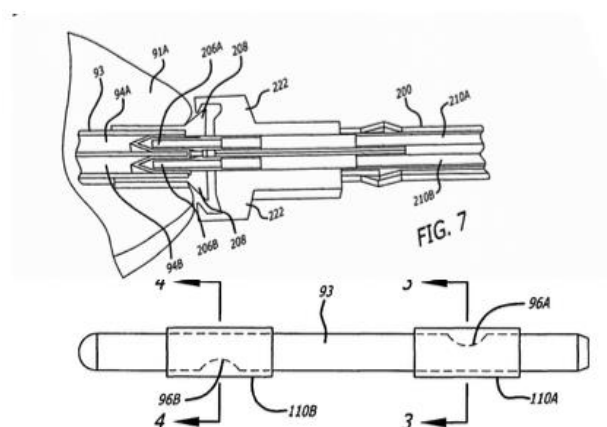
Accordingly, on information and belief, the ReShape Balloon's flexible member is in fluid communication with the valve system.

220. Claim 5 generally recites the gastric balloon structure of claim 4, wherein the flexible member encloses an inflation lumen for introducing the fluid into the at least two isolated non-concentric inflatable chambers.

221. Upon information and belief, the Infringing Instrumentalities infringe claim 5 of the '367 patent. The chambers of the ReShape balloons are filled after they are positioned in the patient's stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. "The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage." *Id.*; see also <https://www.youtube.com/watch?v=U91FsjtMf3o>. The flexible member element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. See <https://reshapeready.com/reshape-cc/>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible member as shown below:



Accordingly, on information and belief, the ReShape Balloon's flexible member encloses an inflation lumen for introducing the fluid into the at least two isolated non-concentric inflatable chambers.

222. Claim 6 generally recites the gastric balloon structure of claim 1, wherein the gastric balloon structure is configured to maintain the inflated state volume of each of the at least two isolated non-concentric inflatable chambers while deployed in the gastric cavity of the patient without controlled adjustment.

223. The Infringing Instrumentalities infringe claim 6 of the '367 patent. The ReShape dual balloons are both filled with saline and remain at a generally fixed volume until they are removed. *See*

1 <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
2 content/uploads/2015/07/ReShape_Instructions_For_Use.pdf, Sec. 2.1 – 2.7 at p.
3 15-16, [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
4 content/uploads/2015/07/ReShape_Instructions_For_Use.pdf.

5 224. Claim 7 generally recites the gastric balloon structure of claim 1,
6 wherein each chamber of the at least two isolated non-concentric inflatable
7 chambers is filled with a same fluid.

8 225. The Infringing Instrumentalities infringe claim 7 of the ‘367 patent.
9 The ReShape dual balloons are both filled with saline and remain at a fixed
10 volume until they are removed. *See*
11 <https://www.youtube.com/watch?v=U91FsjtMf3o>; [https://reshapeready.com/wp-](https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf)
12 content/uploads/2015/07/ReShape_Instructions_For_Use.pdf, Sec. 2.1 – 2.7 at p.
13 15-16.

14 226. Claim 11 generally recites the gastric balloon structure of claim 1,
15 wherein, upon inflation, the gastric balloon structure is configured to rest within
16 the gastric cavity without exerting pressure at any point in the gastric cavity
17 sufficient to cause abrasion, pressure induced lesions, or other trauma.

18 227. The Infringing Instrumentalities infringe claim 11 of the ‘367 patent.
19 The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual
20 gastric balloon is designed to conform to the patient’s anatomy and enhance
21 tolerability.” *See* <http://pro.reshapeready.com/about-reshape/#theadvantages>.
22 Accordingly, on information and belief, it is configured to rest within the gastric
23 cavity without exerting pressure at any point in the gastric cavity sufficient to
24 cause abrasion, pressure induced lesions, or other trauma.

25 228. Claim 12 generally recites the gastric balloon structure of claim 11,
26 wherein an outer surface of each of the isolated non-concentric inflatable
27 chambers is configured to align against greater and lesser curvatures of the gastric
28 cavity.

229. The Infringing Instrumentalities infringe claim 12 of the '367 patent. The ReShape Dual Balloon mimics "the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient's anatomy and enhance tolerability." See <http://pro.reshapeready.com/about-reshape/#theadvantages>.



The conformance of the dual balloon to the stomach of the patient is shown in the image above and is also illustrated in Figure 1 of ReShape's instructions for use, reproduced below.

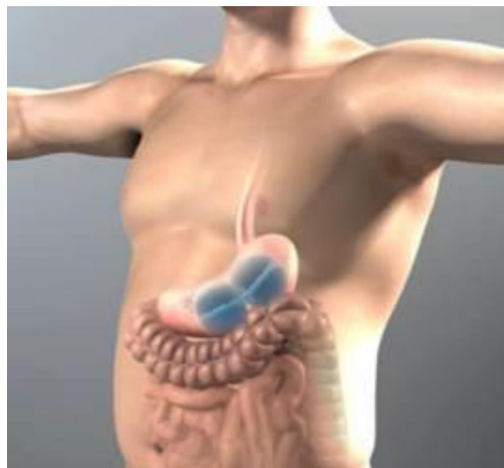


Figure 1. *ReShape* Dual Balloon in the Stomach

Accordingly, on information and belief, an outer surface of each of the isolated non-concentric inflatable chambers is configured to align against greater and lesser curvatures of the gastric cavity.

230. Claim 16 of the ‘367 patent generally recites “An obesity treatment system for deployment in a stomach of a patient such that the system is free-floating and untethered after deployment, comprising: a plurality of adjacent, non-concentric, spaced apart inflatable space-filling compartments, wherein each compartment of the plurality of inflatable space-filling compartments has a respective inflated state volume during treatment of the patient[.]” The Infringing Instrumentalities infringe claim 16 of the ‘367 patent. The ReShape Dual Balloon “is a temporary implant designed to facilitate weight loss by occupying space in the stomach.” ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf; *see also* <https://reshapeready.com/reshape-cc/>. The figures below, taken from ReShape’s instruction manual and documentation, show the dual balloon untethered in a patient’s stomach. The ReShape website states that “[i]n the unlikely event of individual gastric balloon leakage or deflation, the independently sealed *ReShape* weight loss balloons are designed to minimize risk of migration or obstruction.” <http://pro.reshapeready.com/about-reshape/#theadvantages>. In other words, each balloon inflates and deflates independently and its inflated volume is maintained. *See also* <https://www.youtube.com/watch?v=U91FsjtMf3o>.



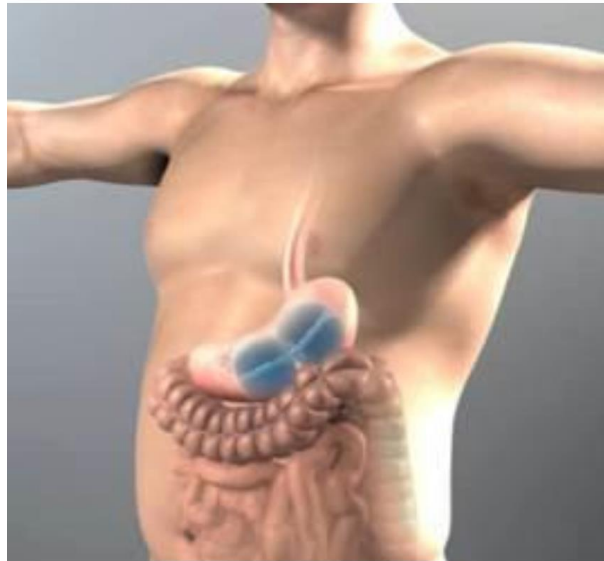
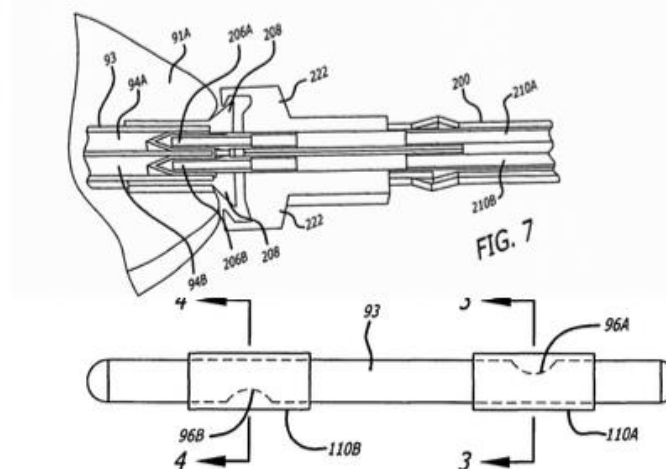


Figure 1. ReShape Dual Balloon in the Stomach

231. Claim 16 further recites “at least two valves to introduce at least one fluid into each of the plurality of inflatable space-filling compartments and to retain, after inflation, fluid in the plurality of inflatable space-filling compartments[.]” The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; U.S. Pat. No. 8,142,469 at Fig. 1, 3-5.

232. Claim 16 further recites “wherein each valve is a one-way valve and wherein at least one of the at least two valves has a proximal end configured to removably attach to an inflation tube[.]” The chambers of the ReShape balloons are filled after they are positioned in the patient’s stomach. ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, pp. 16-17, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf. The instructions state: “Connect the inflation tubing to the proximal balloon fill tube (catheter

lanyard 1) and inflate to the desired volume. Monitor inflation under endoscopic visualization.” *Id.* at 17. “The ReShape™ Valve Sealant is necessary to seal the device valves and prevent balloon leakage.” *Id.*; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>; Further, ReShape’s patent, U.S. 8,142,469, shows a one-way valves as shown below at 206A and 96A:



Accordingly, on information and belief, the each valve of the ReShape Balloon is a one-way valve and at least one of the at least two valves has a proximal end configured to removably attach to an inflation tube.

233. Claim 16 further recites “wherein the plurality of inflatable space-filling compartments form, upon at least partially filling the plurality of inflatable space-filling compartments, a dual balloon system that is configured to float within the stomach; wherein the dual-balloon system is configured to float freely in the patient’s stomach and is not connected to any catheter, lumen or tether after deployment in the patient’s stomach[.]” The video on ReShape’s website shows how the dual balloon structure floats within the stomach without use of a catheter, lumen or other tether. <https://reshapeready.com/reshape-cc/>. A frame from that video is reproduced below.



The ability of the dual balloon to float within the stomach of the patient without a tether is also illustrated in Figure 1 of ReShape’s instructions for use, reproduced below.

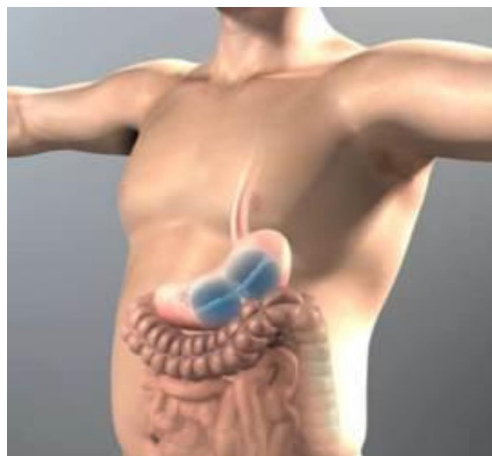


Figure 1. *ReShape* Dual Balloon in the Stomach

234. Lastly, claim 16 recites “wherein, upon inflation, the dual balloon system is configured to float within the stomach without exerting pressure at any point in the stomach sufficient to cause abrasion, pressure induced lesions, or other trauma.” The ReShape Dual Balloon mimics “the natural curvature of the stomach, the dual gastric balloon is designed to conform to the patient’s anatomy and enhance tolerability.” See <http://pro.reshapeready.com/about-reshape/#theadvantages>. Accordingly, on information and belief, it is configured to rest within the gastric cavity without exerting pressure at any point in the

1 gastric cavity sufficient to cause abrasion, pressure induced lesions, or other
2 trauma.

3 235. Claim 17 generally recites the obesity treatment system of claim 16,
4 wherein an outer surface of each of the inflatable space-filling compartments
5 abuts a greater or lesser curvature of the stomach.

6 236. The Infringing Instrumentalities infringe claim 17 of the '367 patent.
7 The ReShape Dual Balloon mimics "the natural curvature of the stomach, the dual
8 gastric balloon is designed to conform to the patient's anatomy and enhance
9 tolerability." See <http://pro.reshapeready.com/about-reshape/#theadvantages>.



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17 The conformance of the dual balloon to the stomach of the patient is shown in the
18 image above and is also illustrated in Figure 1 of ReShape's instructions for use,
19 reproduced below.

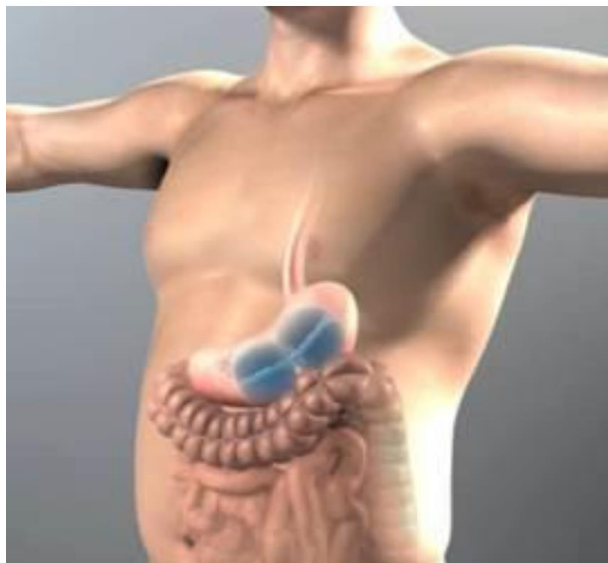


Figure 1. *ReShape* Dual Balloon in the Stomach

Accordingly, on information and belief, an outer surface of each of the inflatable space filling compartments abuts a greater or lesser curvature of the stomach.

237. Claim 18 generally recites the obesity treatment system of claim 16, wherein the plurality of inflatable space-filling compartments are untethered in the stomach after inflation.

238. The Infringing Instrumentalities infringe claim 18 of the '367 patent. The following images below from ReShape's website and instruction manual demonstrate that the ReShape Balloon is untethered in the stomach after inflation. *See generally* <https://reshapeready.com/reshape-cc/>; ReShape™ Integrated Dual Balloon System Instructions for Use, PN 03-0300 Rev. D, p. 1, https://reshapeready.com/wp-content/uploads/2015/07/ReShape_Instructions_For_Use.pdf.

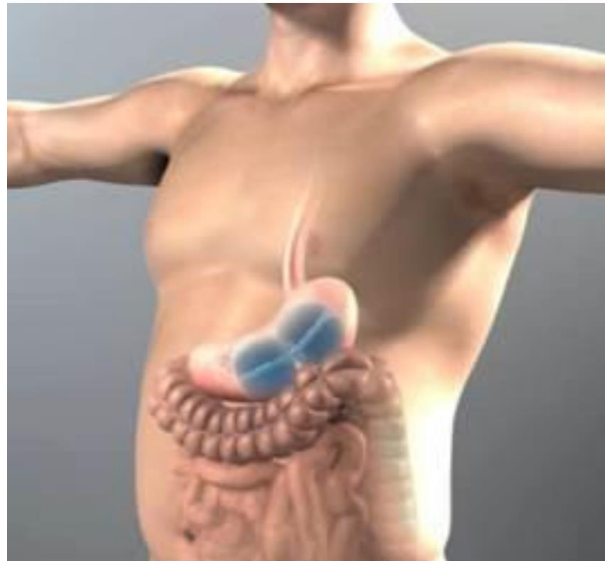
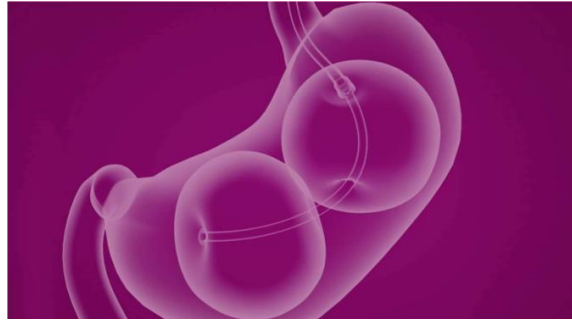


Figure 1. *ReShape* Dual Balloon in the Stomach

239. Claim 19 generally recites the obesity treatment system of claim 16, further comprising a flexible central spine structure spanning a gap between and connecting the plurality of adjacent, spaced apart inflatable space-filling compartments.

240. The Infringing Instrumentalities infringe claim 19 of the '367 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below. *See* <https://reshapeready.com/reshape-cc/>; *see also* <https://www.youtube.com/watch?v=U91FsjtMf3o>.

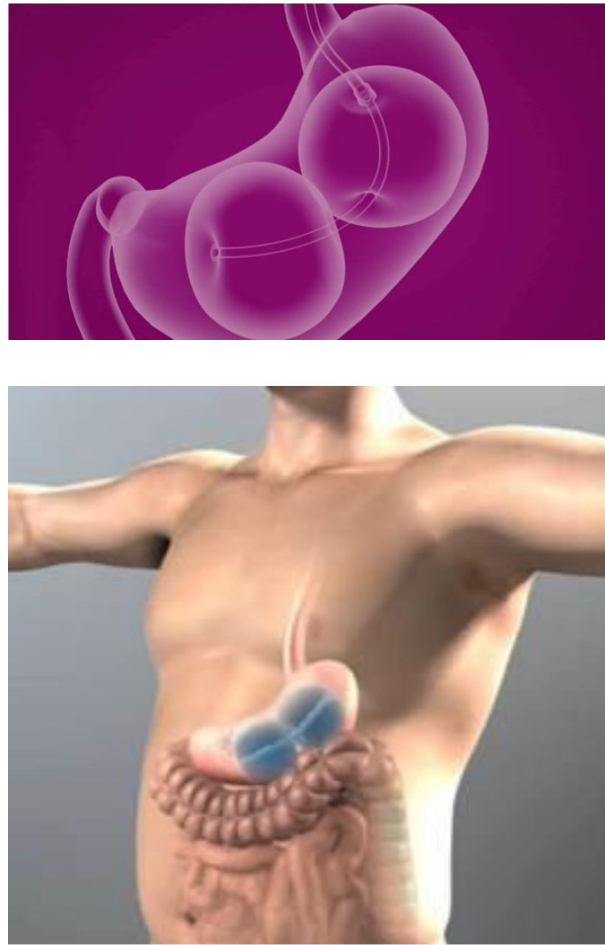


Figure 1. *ReShape* Dual Balloon in the Stomach

Accordingly, on information and belief, the ReShape Balloon's flexible central spine structure spans a gap between and connects the plurality of adjacent, spaced apart inflatable space-filling compartments.

241. Claim 20 generally recites the obesity treatment system of claim 19, wherein the flexible central spine structure is in fluid communication with the valve system.

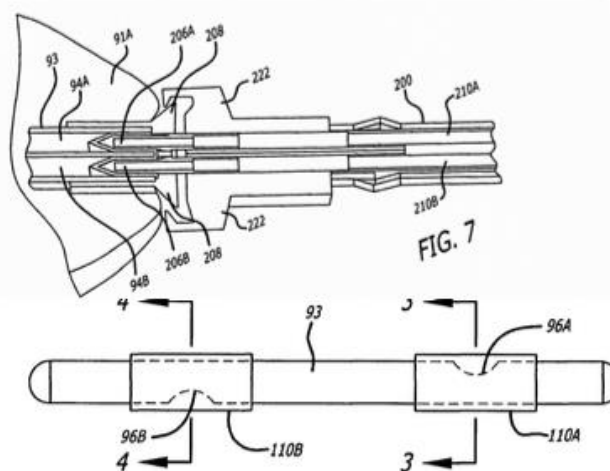
242. Upon information and belief, the Infringing Instrumentalities infringe claim 20 of the '367 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below.

See <https://reshapeready.com/reshape-cc/>; see also

<https://www.youtube.com/watch?v=U91FsjtMf3o>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



Accordingly, on information and belief, the ReShape Balloon's flexible central spine structure is in fluid communication with the valve system.

243. Claim 21 generally recites the obesity treatment system of claim 20, wherein the flexible central spine structure encloses an inflation lumen for introducing the fluid into the plurality of inflatable space-filling compartments.

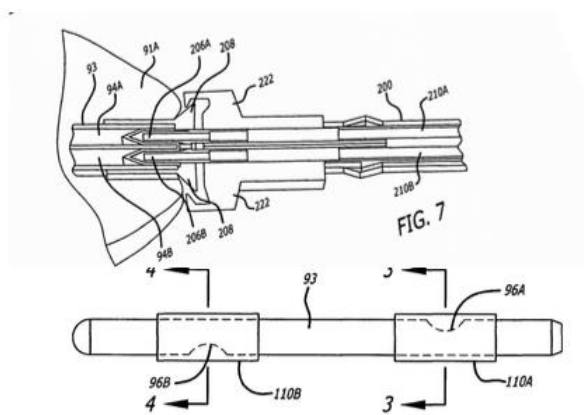
244. Upon information and belief, the Infringing Instrumentalities infringe claim 21 of the '367 patent. The flexible central spine element is illustrated in the video provided on ReShape's website, a frame from which is reproduced below.

See <https://reshapeready.com/reshape-cc/>; *see also*

<https://www.youtube.com/watch?v=U91FsjtMf3o>.



Further, ReShape's patent, U.S. 8,142,469, shows that the inflation lumens and valves are carried by the flexible central spine as shown below:



Accordingly, on information and belief, the ReShape Balloon's flexible central spine structure encloses an inflation lumen for introducing the fluid into the plurality of inflatable space-filling compartments.

245. On information and belief, the Infringing Instrumentalities are used marketed, provided to, and/or used by or for each of ReShape Medical LLC and ReShape Lifesciences' partners, clients, customers and end users across the country and in this District.

246. On information and belief, each of ReShape Medical LLC and ReShape Lifesciences has been aware of the existence of the '367 patent since its issuance.

247. On information and belief, since at least the time each of ReShape Medical LLC and ReShape Lifesciences has been aware of the '367 patent, it has

1 induced and continues to induce others to infringe at least one claim of the '367
2 patent under 35 U.S.C. § 271(b) by, among other things, and with specific intent
3 or willful blindness, actively aiding and abetting others to infringe, including but
4 not limited to each of ReShape Medical LLC and ReShape Lifesciences' partners,
5 clients, customers, and end users, whose use of the ReShape Medical Duo Balloon
6 constitutes direct infringement of at least one claim of the '367 patent.

7 248. In particular, each of ReShape Medical LLC and ReShape
8 Lifesciences' actions that aid and abet others such as its partners, customers,
9 clients, and end users to infringe include advertising and distributing the ReShape
10 Medical Duo Balloon, and providing instruction materials, training, and services
11 regarding the ReShape Medical Duo Balloon. On information and belief, each of
12 ReShape Medical LLC and ReShape Lifesciences has engaged in such actions
13 with specific intent to cause infringement or with willful blindness to the resulting
14 infringement because, on information and belief, it has had actual knowledge of
15 the '367 patent and knowledge that its acts were inducing infringement of the '367
16 patent since at least the date the '367 patent issued.

17 249. Upon information and belief, each of ReShape Medical LLC and
18 ReShape Lifesciences is liable as a contributory infringer of the '367 patent under
19 35 U.S.C. § 271(c) by offering to sell, selling and importing into the United States
20 gastric balloon technology to be especially made or adapted for use in an
21 infringement of the '367 patent. The Infringing Instrumentalities are a material
22 component for use in practicing the '367 patent and are specifically made and are
23 not a staple article of commerce suitable for substantial non-infringing use.

24 250. ReShape Medical LLC and ReShape Lifesciences' infringement of
25 the '367 patent has been, and continues to be knowing, intentional, and willful, in
26 whole or in part because each of ReShape Medical LLC and ReShape
27 Lifesciences has been aware of the '367 patent since its issuance and continues to
28 engage in infringing conduct. ReShape Medical, Inc. had knowledge of all major

1 aspects of Fulfillium's business plans, including trade secrets divulged pursuant to
2 an oral agreement of confidentiality. ReShape Medical, Inc. knew that Fulfillium
3 was actively engaged in patenting its gastric balloon technology. Further,
4 ReShape Medical, Inc. was fully aware that its technology would copy many
5 aspects of Dr. Chen's inventions because it was developed after and with
6 knowledge of Dr. Chen's designs. The fact that ReShape Medical, Inc. knew of
7 Dr. Chen's patents and believed those patents to be relevant to ReShape Medical,
8 Inc.'s gastric balloon technology is demonstrated by ReShape Medical, Inc.'s
9 citation of Dr. Chen's patents as relevant prior art when attempting to procure its
10 own patents. For instance, in December 2012 ReShape Medical, Inc. filed an
11 information disclosure statement with the United States Patent and Trademark
12 Office indicating that Dr. Chen's previous patent applications were relevant to
13 ReShape Medical, Inc.'s pending patent application directed to the ReShape
14 Balloon. Additionally, ReShape Medical, Inc. (and consequently ReShape
15 Medical LLC and ReShape Lifesciences) received explicit notice of the '367
16 patent via letter on November 14, 2017.

17 251. Each of ReShape Medical LLC and ReShape Lifesciences' acts of
18 infringement of the '367 patent have caused and will continue to cause Fulfillium
19 damages for which Fulfillium is entitled to compensation pursuant to 35 U.S.C. §
20 284.

21 252. Each of ReShape Medical LLC and ReShape Lifesciences' acts of
22 infringement of the '367 patent have caused and will continue to cause Fulfillium
23 immediate and irreparable harm unless such infringing activities are enjoined by
24 this Court pursuant to 35 U.S.C. § 283. Fulfillium has no adequate remedy at law.

25 253. This case is exceptional and, therefore, Fulfillium is entitled to an
26 award of attorneys' fees pursuant to 35 U.S.C. § 285.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands a trial by jury on all issues triable as such.

PRAYER FOR RELIEF

WHEREFORE, Fulfillium respectfully requests that the Court enter judgment against Defendants as follows:

A. An adjudication that each of ReShape Medical LLC, Intersect Partners, and SV Health has misappropriated and conspired to misappropriate Fulfillium's trade secrets;

B. An adjudication that Fulfillium have judgment against each of Defendants for compensatory damages, unjust enrichment, and/or disgorgement in an amount not less than the sum of \$50 million;

C. An adjudication that Fulfillium have judgment against each of ReShape Medical LLC, Intersect Partners, and SV Health for exemplary damages under Civil Code § 3624.3(c) and/or Mass. Gen. Laws ch. 93, § 42-42A in the amount not less than twice the amount of Fulfillium's actual damage or the amounts by which each of ReShape Medical LLC, Intersect Partners, and SV Health has been unjustly enriched;

D. An adjudication that each of Defendants be ordered to deliver up to Fulfillium all documents, electronic and otherwise, containing Fulfillium trade secret information, and all products developed using such information;

E. An adjudication that each of Defendants and their subsidiaries, affiliates, parents, successors, assigns, officers, agents, servants, employees, attorneys, and all persons acting in concert or in participation with them, or any of them, be temporarily and preliminarily enjoined during the pendency of this action, and permanently enjoined thereafter, from further misappropriation, disclosure and/or use of any Fulfillium trade secret information;

1 F. An adjudication that ReShape Medical LLC and ReShape
2 Lifesciences have infringed the ‘915, ‘930, and ‘367 patents in violation of 35
3 U.S.C. § 271;

4 G. A granting of an injunction permanently enjoining ReShape Medical
5 LLC and ReShape Lifesciences, its employees, agents, officers, directors,
6 attorneys, successors, affiliates, subsidiaries and assigns, and all of those in active
7 concert and participation with any of the foregoing persons or entities from
8 infringing, contributing to the infringement of, or inducing infringement of the
9 ‘915, ‘930, and ‘367 patents;

10 H. An order to ReShape Medical LLC and ReShape Lifesciences to
11 account and pay damages adequate to compensate Fulfillium for ReShape Medical
12 LLC and ReShape Lifesciences’ infringement of the ‘915, ‘930, and ‘367 patents,
13 with pre-judgment and post-judgment interest and costs, pursuant to 35 U.S.C.
14 § 284, and an accounting of all infringing acts not presented at trial;

15 I. An order that the damages award be increased up to three times the
16 actual amount assessed, pursuant to 35 U.S.C. § 284;

17 J. A declaration that this case is exceptional under 35 U.S.C. § 285, and
18 an award of Fulfillium’s reasonable costs and fees, including attorneys’ fees, with
19 interest; and

20 K. An award to Fulfillium of such other and further relief as this Court
21 deems just and proper.

1 Dated: August 15, 2018

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22 *Attorneys for Plaintiff Fulfillium, Inc.*

DEMAND FOR A JURY TRIAL

Plaintiff Fulfillium, Inc. requests a trial by jury on all issues for which it is
entitled to a jury.

Dated: August 15, 2018

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